Diabetes Rehabilitation : Effects and Utilisation of a Multidisciplinary Intensive Education Programme

Keers, Johannes Cornelis

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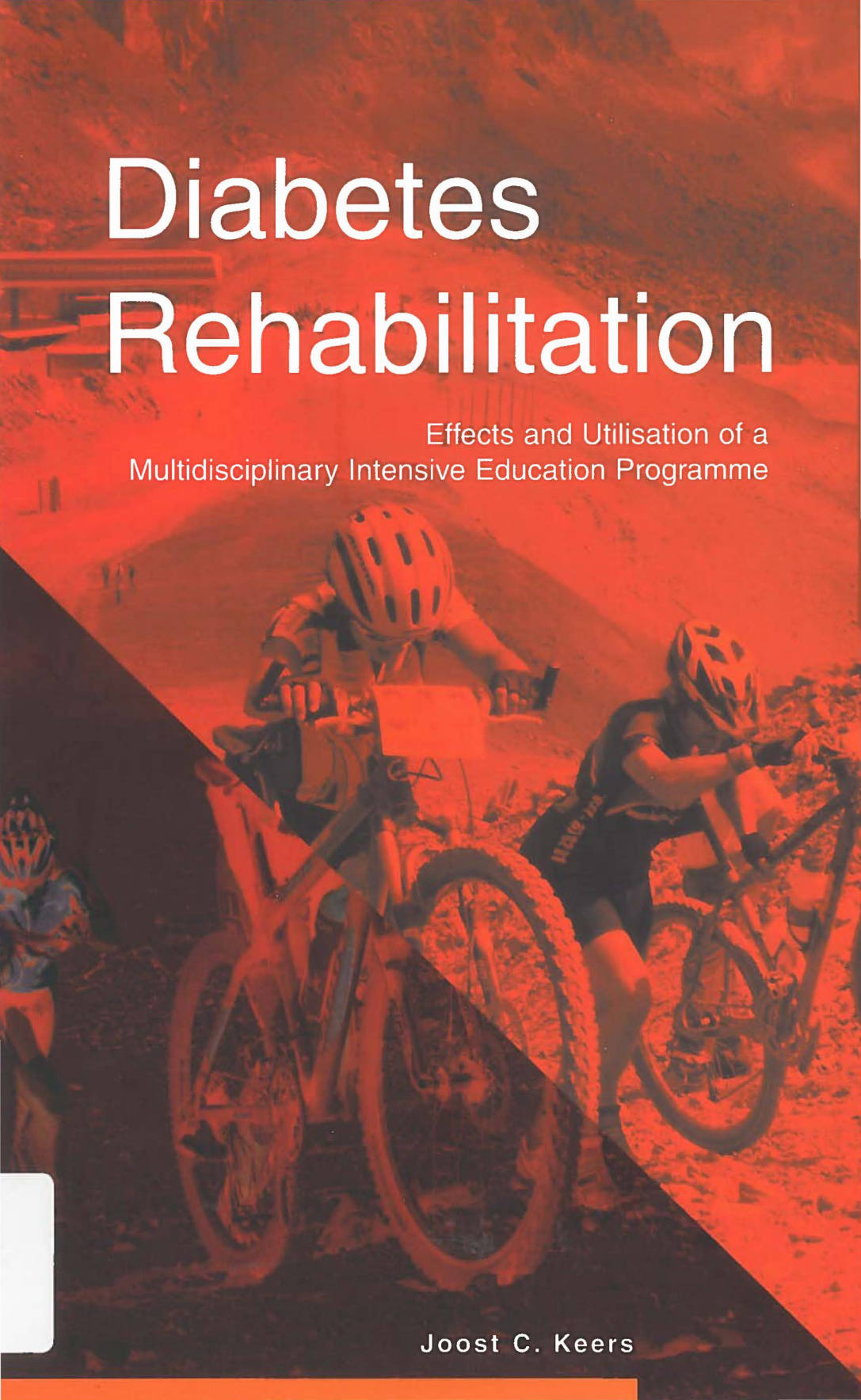

Joost C. Keers

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Stellingen

behorende bij het proefschrift:

Diabetes Rehabilitation:
Effects and Utilisation of a Multidisciplinary Intensive Education Programme

Joost C. Keers

1. Om adequate en effectieve zorg te verlenen is het meten van het psychosociaal functioneren bij mensen met diabetes net zo belangrijk als het bepalen van HbA1c (dit proefschrift).

2. Het is effectiever om diabeteszorg te richten op het patiënten leren bewuste keuzen te maken en strategieën te leren om problemen op te lossen dan als behandelaar problemen voor patiënten proberen te verhelpen (dit proefschrift).

3. De empowerment benadering is de beste optie voor diabeteseducatie omdat zelfmanagement de basis is van de behandeling van diabetes.

4. Het 'Number Needed to Treat' zoals toegepast in Hoofdstuk 5 van dit proefschrift betekent: "Succes is een keuze".

5. Een empowerment benadering in diabeteszorg vraagt niet alleen een andere houding van behandelaars en patiënten, maar ook van de directe omgeving (partner) van de patiënt (dit proefschrift).

6. Een gerandomiseerde gecontroleerde klinische trial zou een beter beeld geven van de effecten van MIEP onder ideale omstandigheden ten koste van de kennis over de bruikbaarheid van MIEP in de klinische praktijk.

7. De opmerking dat de effecten van MIEP aan aandacht voor de patiënt kunnen worden toegeschreven is geen verwijt maar een compliment, omdat aandacht voor de patiënt de kern is van goede diabeteszorg.

8. De bevinding: "Compliance is a very abnormal behaviour pattern in normal adults" (S. Dunn, 1990) is zeer bepalend voor de manier waarop diabeteseducatie gegeven moet worden.

9. Uitbehandelde patiënten met diabetes bestaan niet, uitbehandelde behandelaars wel.

10. "Onderzoekt alles en behoudt het goede" is ook zo'n 2000 jaar na Paulus een goed paradigma voor het doen van onderzoek, maar helaas is het niet haalbaar binnen de beperkte tijd van een AIO project.

11. Vervelend werk moet je uitstellen: immers, van uitstel komt afstel.

12. Om een promotieproject succesvol af te ronden geldt eenzelfde regel als bij mountainbiken: Focus je op je weg, niet op de afgrond ernaast.

13. Bij interventieonderzoek geldt: wil je publiceren, dan moet je randomiseren.

RIJKSUNIVERSITEIT GRONINGEN

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Proefschrift

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Contents

1

General introduction

1.1 Diabetes and its treatment

Diabetes is a common chronic disease with a growing prevalence world-wide (1). In 2001, the International Diabetes Federation estimated the number of people with diabetes in the entire world population (5.8 billion) at 194 million. The world-wide prevalence of diabetes in the 20-79 age group was estimated at 5.2% and its prevalence in Europe at 5.5%. There are different ways of determining the number of people with diabetes in the Netherlands. The National Institute for Public Health and the Environment (RIVM) combines several sources and estimates the total number of known cases between 474 and 508 thousand (2). Beside these diagnosed diabetic patients there is a great number of people with diabetes who have not yet been diagnosed as such. The World Health Organisation (WHO) distinguishes a number of different forms of diabetes (3), of which type 1 and type 2 are the most common. It is these forms of diabetes that this thesis is concerned with.

Type 1 diabetes is usually contracted at a fairly early age, typically before the age of 20; 10-15% of all diabetic patients have type 1 diabetes (1;2). In this type of diabetes, the beta cells of the islets of Langerhans in the pancreas are destroyed, resulting in a stop in the production of insulin. It is likely that an auto-immune reaction plays an important role in the development of type 1 diabetes. Because there is no insulin in the body, glucose cannot be stored in muscular tissue and the liver, severely raising blood glucose levels. Treatment of type 1 diabetes consists of insulin substitution therapy, in which patients can administer the required dose usually by means of subcutaneous injections. In addition, patients make use of insulin pumps which can continuously administer the required dose of insulin. With the help of a blood glucose meter and a drop of blood obtained by a finger prick, patients can determine their current blood glucose level themselves. The blood glucose values thus obtained are necessary to determine the correct dosage of insulin.

Type 2 diabetes is usually contracted later in life, although the number of patients developing type 2 diabetes before the age of 40 is growing because of an increase in the number of people with obesity and a sedentary lifestyle (1). About 85 to 90% of all diabetic patients have type 2 diabetes (1;2), and this number will continue to rise (4). In type 2 diabetes there is a relative deficiency in insulin because the body tissue is to a certain extent resistant to it and the pancreas cannot compensate for the increased demand for insulin. Hereditary factors, obesity and a lack of exercise can all contribute to the development of type 2 diabetes. Treatment of type 2 diabetes consists of a specially adapted diet and medication which increases insulin production and/or heightens insulin sensitivity. In time, however, treatment with insulin is often also necessary to lower raised blood glucose levels.

The primary goal of treatment for both type 1 and type 2 diabetes is to normalise blood glucose levels. The percentage of glycosylated

haemoglobin, HbA1c, is the most important measure of glycaemic control and reflects the mean blood glucose values of the preceding 6 to 8 weeks. The goal of diabetes treatment is to attain HbA1c values that resemble the values of people without diabetes as closely as possible (reference values for healthy people: 4.3-6.1%). HbA1c levels below 7.0% are considered good glycaemic control, whereas levels above 8.0% indicate poor glycaemic control (5). In both type 1 and type 2 diabetes, prolonged poor metabolic control increases patients' risk of developing microvascular complications (6;7) such as neuropathy, retinopathy or nephropathy. After a period of 15 years, 2% of all people with diabetes are blind, 10% have severely limited eyesight, and 20% suffer from kidney failure; in addition, diabetes is the main cause of non-traumatic amputations (1). Of course, these complications have a strong negative influence on the quality of life of these patients (8;9). Apart from preventing the occurrence of hyperglycaemia (blood glucose levels that are too high), blood glucose values that are too low are not desirable. These hypoglycaemia can cause various acute symptoms ranging from dizziness to unconsciousness; even death can be a consequence.

The medical developments of the last three decades have changed the treatment of diabetes from a rigid regimen into a more dynamic approach. The development of increasingly advanced blood glucose meters and the development of short acting insulin gives patients more freedom and flexibility in the regulation of their blood glucose levels. Self-regulation enables patients to adapt their medication to their own lives and makes them better prepared to deal with unexpected events. This means that diabetes has more and more become a disease whose treatment relies on self-management. The biggest effort to regulate diabetes is made by patients themselves (1;10;11), every day and all their lives.

Diabetes education is the obvious and generally acknowledged way to provide patients with the knowledge and the skills that are needed for adequate self-care (12;13). The importance of diabetes education was already mentioned by F.G. Banting in the speech he delivered on the occasion of winning the Nobel prize for Physiology or Medicine (1923) for the invention of insulin (14): "All diabetics who have not an adequate knowledge of the dietetic treatment of their disease should be admitted to hospital in order that they may receive instruction in the preparation of their calculated and weighed diet - that they may learn the qualitative tests for sugar and acetone in the urine - that their carbohydrate tolerance may be accurately determined; and that the use of insulin, if required, may be safely instituted". In spite of diabetes education and recent technical developments with respect to self-regulation only a limited number of people with diabetes turn out to have good diabetes regulation, and diabetes complications are still common (1;3). For instance, only 19% of the outpatient diabetic patients of the Groningen University Hospital have HbA1c values below 7.0%, whereas 42% of these patients have HbA1c levels above 8.0%. There is therefore room for improvement.

1.2 Psychology in diabetes care

As described above, technical developments with respect to insulin and improved possibilities for self-control have enabled more flexible self-management. People with diabetes do no longer have to keep to a strict insulin schedule combined with prescribed meals, and are therefore better able to adapt to unexpected events. At the same time it is possible to effect lower mean blood sugar values, which reduces the risk of complications (6;7).

The increased possibilities for self-management may provide more freedom of choice but do not automatically mean that it has become easier to adapt to a life with diabetes. It is largely diabetic patients' own responsibility to maintain the right balance between insulin dosage, physical exercise and nutrition. This means that patients need to determine their blood glucose levels very regularly and be on the alert for signs of deregulation.

Diabetes requires lifelong active daily efforts from patients and this health behaviour eventually can determine their well-being and health to a great extent (10). Health behaviour, however, depends on many factors which can impede adaptation to a life with diabetes and which can constitute an obstacle to optimal self-management. For this reason, diabetes is considered one of the psychologically most burdensome diseases (15).

1.2.1 Models of health behaviour

From a health psychological point of view, a number of general models have been developed, which can provide insight into the factors determining whether someone will engage in health-promoting behaviour. These models can be useful for both research in health behaviour and clinical practice in exploring the most relevant aspects of diabetic patients' health behaviour. Some well-known models aiming to explain health behaviour and changes in this behaviour are the *health belief model* (16), the *theory of reasoned action* (17), the *theory of planned behaviour* (18) and the *transtheoretical model of behaviour change* (19). These models have also been used in research in self-management in diabetes and in diabetes education. They will be briefly discussed below.

The health belief model (16) describes how perceived threat and perceived costs and benefits influence the probability that someone engages in health-promoting behaviour. However, although the elements of the health belief model prove to be statistically related to self-management in diabetes (20), the total variance the model can explain is limited (21), i.e., the model only partially describes how self-management comes about. The theory of reasoned action (17) assumes that the intention for a particular kind of behaviour is the only and best predictor of someone's actual behaviour. This intention is determined by a person's attitudes towards the health behaviour in question and by the subjective norms regarding to this behaviour. The development of these subjective norms is determined in part by someone's

immediate surroundings. The concept of perceived behavioural control - which is conceptually equal to self-efficacy- was later added to the Theory of Reasoned Action; the revised model is known as the Theory of Planned Behaviour (18). The Theory of Planned Behaviour especially gives valuable information for explaining active self-care behaviour on specific components of self-management such as home blood glucose monitoring and self-adjustment of the insulin dose (22). The transtheoretical model of behaviour change (19) describes the different stages of behaviour change. This model seems especially useful for the planning and guidance of behaviour changes in outpatient settings, although its usefulness in the treatment of diabetes has not extensively been tested yet (23).

These general models provide insight into the factors influencing diabetes education and self-management, but assume clearly defined behaviour, e.g., "eat an apple a day...". Self-management in diabetes, however, consists of a complex set of activities which may vary per individual. It is therefore difficult to define good self-management (24), which means that the general health psychological models are often limited in their usefulness to describe the psychological determinants of self-management as a whole in diabetes as well as in their usefulness for developing intervention programmes. The model for diabetes education developed by Glasgow and Osteen (25) aptly describes the variety of variables affecting diabetes self-management, and, ultimately, glycaemic control and health-related quality of life. Without making explicit all possibilities, the model describes the role of process and mediating variables. In this thesis, several of these variables are studied, namely diabetes-related health locus of control, diabetes-related coping styles and knowledge of diabetes. Health locus of control and diabetes-related coping styles refer to the attitudes diabetic patients have towards their disease and to the way in which and the extent to which they themselves play a role in its treatment and the outcomes of this treatment. According to the empowerment approach (26-28), which will be discussed in more detail in paragraph 1.2.2, these variables form important aspects of the desired effects of diabetes education.

Glasgow and Osteen's model also acknowledges the role of the surroundings and the social context of a patient participating in an intervention. They claim that it is especially prior to an intervention that this social context is important in the description of the target group, and that social context is directly related to self-management behaviour (25). This means that particularly spousal behaviour may affect intervention outcomes. Motivating surroundings in the form of an involved but not overprotective partner are necessary to convert intentions into self-management behaviour in everyday life.

The chronic nature and great impact of diabetes self-management on everyday life (15) can make it difficult for patients to make permanent changes to their lifestyle. Besides, optimal diabetes regulation also has its

disadvantages, such as an increase in the occurrence of hypoglycaemia (6), and self-management in diabetes often interferes with other important aspects in life. In a self-help book for diabetic patients, Polonsky (29) states that patients put in a great deal of effort to maintain self-management but experience few benefits and little control, while they are aware of the imminence of complications. This may lead to what he refers to as 'diabetes burnout'. These feelings of frustration and powerlessness combined with the feeling that self-management requires too much effort, can result in a neglect of self-care and in poorer glycaemic control.

1.2.2 From compliance to empowerment

Because of the impact that diabetes and its treatment have on patients' lives as outlined above, support and education are essential. Diabetes education is a generally accepted component of diabetes treatment (12); there is less consensus, however, on the method of education and the goals intended (30). Roughly, two approaches with respect to diabetes education can be distinguished: the compliance-based approach and the patient empowerment approach (26;31). The former refers to a more traditional, biomedically oriented education which expects patients to follow the prescriptions of a health-care professional. The most important aspect of compliance-based education is the transfer of knowledge. However, although knowledge of diabetes is essential, it is certainly not sufficient to ensure good diabetes regulation (11;32).

Because the treatment of diabetes has such a large behavioural component (11), diabetes education requires a more biopsychosocial empowerment-based approach (33-35). In the treatment of diabetic patients, personal lifestyles, habits and values also need to be taken into account. The contribution made by the patients themselves -positive or negative- is ultimately the most important determinant of the success of treatment (10). The application of this information in diabetes care requires that both patients and health-care professionals assume a different role (36). The latter are expected to assume a coaching role in which they support patients in making informed choices (26). For patients the objective is to play a more active part in their treatment and to work towards self-selected goals (10;27). There are a number of interventions which are explicitly based on the empowerment approach (10;27;28); the rehabilitation programme described in this thesis is also an example of such an intervention (37).

In the last few years, the concept of 'empowerment' has been used more and more in the diabetes literature. Before the year 1991, the literature search programme 'Silverplatter Medline' does not give any results for the combined entry 'diabetes' and 'empowerment'. From 1991 to 1995, 11 articles are found using these terms; between 1996 and 2001, 23 articles, and from 2001 to March 2004 39. In spite of this increase in publications on

empowerment and a greater familiarity with the concept of empowerment, its operationalisation is not uniform across the different studies. It is important to make a distinction between empowerment as an approach or philosophy of diabetes treatment (31) and empowerment as an outcome of this approach, in the sense of 'empowered patients' (26).

There are a few studies on psychologically oriented interventions aimed at patients with self-management problems (38). In a recent article, Snoek and Skinner (39) describe 11 randomised clinical trials concerning the treatment of five psychological problems that are common in diabetic patients, namely depression, eating disorders, anxiety/stress, self-destructive behaviour, and interpersonal conflicts. To our knowledge, only one study (40) reports the positive effects of a more general multifocus education programme for patients who failed to achieve their therapeutic goals in spite of intensive regular care. Both the target group and the approach taken by this intervention programme closely match that of the Multidisciplinary Intensive Education Programme (MIEP).

Various aspects of intensive education programmes are known to contribute to their effectiveness. These relatively time-consuming and expensive programmes have to aim at a target group of patients who experience many self-management problems and for whom regular care proves to be inadequate (41). Many interventions are effective in the short term; the consolidation of the effects, however, is often much less good (42). To attain permanent self-management effects, changes in the attitudes and motivation of a patient are needed (43). Effective programmes are tuned to someone's personal lifestyle, take individual habits into account, facilitate social support and have to be reinforced over time (44). Treatments combining metabolic and psychosocial factors are the most effective. This necessitates close cooperation between diabetologists, diabetes nurse specialists, psychologists and other team members (39).

1.3 Evaluating interventions in practice

In general, a randomised clinical trial is considered the best method to study the effects of an intervention. According to strict protocols, an intervention is administered to an often homogeneous, motivated group of patients. The results of such a randomised clinical trial very clearly demonstrate the efficacy of the treatment as performed in the experimental context of the study. These results, however, often concern non-representative patient populations and non-representative settings (38;45) and do not say enough about a programme's usefulness in the real world in which settings are more complex and less favourable, patients are less motivated and health care providers often do not have much time (46). A good example of the gap between an experimental setting and clinical practice is the extremely

influential DCCT-study (6). Although this is one of the experimentally most impeccably performed studies, it also turns out to be one of the least generalisable (47;48). The great improvement in glycaemic control and decrease in the occurrence of complications obtained in this study were possible because of strict subject selection and participation demands, and because of the quality, intensity en duration of the support the participants in this study received. The purpose of the DCCT-study was to show effects of optimal blood sugar regulation. A strongly improved regulation, then, proves possible, but this does not indicate to what extent these results are attainable in normal clinical practice.

So, the problem with strictly performed controlled randomised clinical trials is their generalisability to clinical practice. Moreover, RCTs cannot always be simply performed in the clinic or setting under study. In these cases, quasi experimental designs (49) have to be used. Although the results of quasi experimental designs have a lower level of clinical evidence, they do apply to real life, which makes it easier to determine their usefulness for clinical practice.

The RE-AIM framework developed by Glasgow and Vogt (50) is a good tool to study and describe the impact or efficiency of an intervention in clinical practice. This framework consists of five dimensions, with the ultimate public health impact being determined by the product of all these dimensions. The table below gives an overview of the dimensions in question, and describes how they are operationalised and whether they are relevant at the individual or the organisational level. Chapter 1.4 discusses how MIEP is studied and how the different parts of this project fit in with the RE-AIM framework.

Table 1: The RE-AIM framework; the public health impact of interventions

Dimension	Measurement	Level
Reach: proportion of patients that will receive, or be willing and able to participate in the intervention	Percentage and representativeness of members of a population that participate	Individual
Efficacy: success rates if implemented as in guidelines	Magnitude or percentage of improvement on outcome(s) of interest	Individual
Adoption: The number of clinics that will adopt the intervention	Percentages and representativeness of organisations or settings that try an intervention	Organisational
Implementation: The extent to what the intervention is implemented as intended in the real world	Consistency and quality of intervention delivered under real world conditions	Organisational
Maintenance: The extent to which a programme is sustained over time	Extent to which settings continue to deliver a program over time	Individual/ organisational

Based on Glasgow and Vogt (50) and Glasgow and Eakin (46).

1.4 The current research project

1.4.1 Background of the project

The development referred to above of improved possibilities for diabetes self-management and an increased role of behavioural sciences in diabetes care, has obviously also taken place in Groningen. In the mid 1990s it became increasingly clear that some diabetic patients had prolonged difficulties maintaining adequate diabetes self-management in spite of intensive outpatient care and optimised medical treatment. These problems manifested themselves in insufficient glycaemic regulation as well as in diabetes-related distress. There was a need for additional diabetes care for a specific subgroup of patients with self-management problems who had not yet developed major complications but who did run a high risk of doing so (6;7;51).

The Department of Diabetes Rehabilitation of the Academic Centre for Rehabilitation (Beatrixoord) already had a clinical department for diabetic patients and offered the possibility for this additional care. Patients were

admitted here, often for a long period of time, which effectively created an environment in which good diabetes regulation was possible. Although a clinical admission is necessary for some patients with prolonged self-management problems, such a clinical environment is not representative for the environment in which self-management is normally performed. During hospitalisation, it is difficult to sufficiently take into account patients' daily life contexts, in which they eventually have to regulate their diabetes. An intensive outpatient intervention would better suit the care needs of MIEP's target group, consisting of relatively young patients without any major complication. For this reason, a 12-day outpatient programme for rehabilitation was started (37) in 1997, involving the departments of Diabetes Rehabilitation, Endocrinology, Internal Medicine, and the Northern Centre for Healthcare Research. Elements that have proven useful in earlier intervention studies have been fitted into the rehabilitation programme wherever possible. This multidisciplinary intensive education programme (MIEP) is based on the empowerment approach (27;31;35). Chapter 2 describes the development and aim of MIEP, and indicates how the empowerment approach is translated into an outpatient rehabilitation programme.

1.4.2 Description of the studies

MIEP arose from a need of clinical practice to improve care for diabetic patients with prolonged self-management problems. This origin has had effects on the research described in this thesis. For example, it has not been possible to perform a randomised clinical trial within the scope of this newly developed rehabilitation programme. Besides, this thesis not only intended to answer the question to what extent MIEP is effective in ideal conditions, but also addressed MIEP's usefulness and application in clinical practice. To this end, four studies were performed as part of the project. Table 2 gives an overview of these studies. The studies among the participants of the rehabilitation programme had a longitudinal design and all made use of the same measurements. Figure 1 shows the basic schedule used in these studies; participants were assessed when they were admitted for rehabilitation, at their second revisit (at the end of rehabilitation), and a year after completion of the programme.

Table 2: studies of the MIEP-project

Study	Description	Design	Participants
Pilot	Pilot study focusing on 3-months effects of MIEP on HbA1c, Health-related quality of life (HR-QoL) and knowledge with the aim to test the programme	pre-post test; measurements at baseline (T0) and 3 months (T1) follow-up	51 participants of MIEP
MIEP-1	Study focussing on effects and mechanisms of effect in MIEP participants. Outcomes were glycemic control, HR-QoL, and determinants of empowerment	Longitudinal study; measurements at baseline (T0), 3 months (T1) and 1 year (T2) follow-up	90 participants of MIEP
MIEP-2	Study comparable to MIEP-1, but outcomes for diabetes-related distress and costs were added and after the main module of MIEP patients were randomised to receiving booster calls	Longitudinal study; measurements at T0, T1 and T2	76 participants of MIEP
MIEP-3	Study of consecutive non-referred outpatients who could be considered 'average diabetic patients', measuring the same outcomes as MIEP-2. Diabetologists stated if they perceived patients eligible for MIEP	Cross-sectional study, with multiple retrospective HbA1c values	231 consecutive outpatients

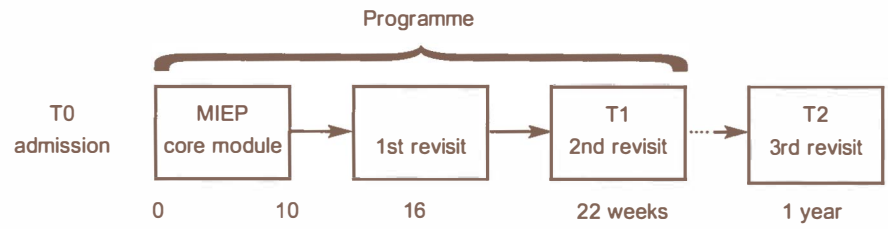

Figure 1: Schedule of the Multidisciplinary Intensive Education Programme

1.4.3 The RE-AIM model and MIEP

The aim of the research described in this thesis is to investigate various aspects contributing to the ultimate impact of MIEP in diabetes care. For an intervention to be run efficiently, it is important that the five aspects of the RE-AIM model are performed well. As is customary, the current study gives much attention to the *efficacy* of the intervention (46;50). In this thesis, outcomes in various domains are described. Not only effects on glycaemic control were considered, but effects on health-related quality of life (HR-QoL), diabetes-related distress, indicators of empowerment and on cost-effectiveness were also considered.

As indicated by the RE-AIM model, the ultimate impact of an intervention is not only determined by its efficacy. For a new form of diabetes care such as MIEP it is important that the right target group is *reached*; in this case the target group consists of diabetic patients with poor glycaemic regulation and/or diabetes-related distress. We investigated what makes diabetologists consider referral to diabetes rehabilitation and to what extent they recognise MIEP's specific target group.

In the *adoption* of MIEP, it is not the number of clinics which are willing to run MIEP as a programme, but the number of outpatient diabetes clinics which refer patients to diabetes rehabilitation that is important. MIEP concerns additional care intended for diabetic patients with prolonged self-management problems from the whole of the North of The Netherlands. Virtually all participants in the pilot study were patients referred by the outpatient diabetes clinic of the Groningen University Hospital. Through the years, however, more and more clinics in the region have started referring patients.

The *implementation* of MIEP is not expressed in numbers in the present study. MIEP has been developed by members of the departments of Endocrinology, Internal Medicine and of the Northern Centre for Healthcare Research already referred to above, with a facilitating role for the department of Diabetes Rehabilitation. MIEP is therefore, in effect, directly implemented in clinical practice. During the period in which the four studies were performed the programme has undergone virtually no changes. Small changes in the programme have always been effected at the same time as the different studies of this project started. For example, after the pilot study it was decided to switch from a two day a week schedule for five weeks to an one day a week schedule for ten weeks.

To determine the eventual clinical usefulness of an intervention, *maintenance* is essential, both for research into intervention and for clinical practice. When after a number of years of maintenance the results of research and practical experiences suggest improvements, it may be a good idea to discontinue and adapt the programme. Obviously, its strong points and useful principles need to be kept in; changes would have to take place on the

basis of progressive insight and not simply on the basis of a need for change. Perhaps the present dissertation can contribute to this progressive insight in intensive treatment of diabetic patients with prolonged self-management difficulties.

1.4.4 Main research questions

This thesis will address the following three main research questions.

1. **What are the effects of MIEP?** What are the effects of MIEP on glycaemic control, HR-QoL, diabetes-related distress, indicators of empowerment? Is MIEP cost-effective?
2. **For whom is MIEP effective?** Which patients benefit the most from MIEP and how can this target group be recognised?
3. **Which factors contribute to the effects of MIEP?** What are the mechanisms underlying the effects of MIEP? Which factors contribute to the effects of glycaemic control and HR-QoL and which elements of the rehabilitation programme are responsible for this?

1.5 Outline of the thesis

This thesis deals with four studies concerning diabetes rehabilitation, which are usually discussed jointly in the different chapters. For example, the participants' functioning before and after rehabilitation is compared with that of the control group of average outpatient diabetic patients. The studies and chapters in this thesis help determine the effects of MIEP and contribute to the discussion about the clinical application of MIEP.

Chapter 2 describes the pilot study and pays detailed attention to the development of the empowerment-based rehabilitation programme in detail. Furthermore, it deals with the goals of the different subparts of MIEP, the content of the programme, and the way in which rehabilitation is conducted. Many intervention studies lack a good description of the intervention (30;42), which makes replication and application to other/different settings difficult. Because of the action research character of the MIEP study, detailed attention has been paid to the description of the intervention in this pilot study. The 3-months follow-up effects of the pilot study on glycaemic control, HR-QoL, diabetes-related symptoms, health locus of control and knowledge of diabetes are discussed. The predictors of changes in the main effect measures were analysed using regression analyses.

Chapter 3 deals with the short-term effects of rehabilitation on glycaemic control, HR-QoL and indicators of empowerment. Special attention is paid to the heterogeneity of the group of patients participating in MIEP, who all have different personal goals and reasons for referral. Obviously all

participants have self-management problems, but these can manifest themselves in different ways. For these different groups of patients, different outcomes are therefore relevant. To be able to describe the consequences of treating a heterogeneous group of patients for the effects of MIEP, the participants of MIEP-1 were divided into subgroups on the basis of their baseline HbA1c and baseline mental functioning. These two variables turn out to be good predictors of the main problems that patients referred to MIEP have. The effects were then determined for each of the subgroups. The group of participants as a whole and its subgroups were compared to the reference group of MIEP-3.

Chapter 4 deals with the 1-year effects of MIEP. Changes over time in the patients of MIEP-1, supplemented with some participants of MIEP-2 (only patients who were not called as part of a telephonic booster sessions) were analysed, as well as the determinants of these changes. This chapter describes the extent to which patients have developed more feelings of empowerment during MIEP contributes to treatment outcomes 3 months after the completion of MIEP. In addition, it was examined to what degree changes in indicators of empowerment after rehabilitation (3-12 months follow-up) contribute to the improvements in HbA1c levels and HR-QoL or to further improvements herein.

Part of the MIEP project was performed as part of a health technology assessment. Especially *chapter 5*, which compares the costs and benefits of MIEP, is strongly based on this assessment. For the application and maintenance of an intensive additional intervention, it is important to know to what extent the benefits offset the costs. On the basis of various indicators direct and indirect medical costs of rehabilitation for the participants of MIEP-2 and MIEP-3 were compared; this was done one year retrospectively at baseline of MIEP and at one year follow-up. The mean costs of MIEP per patient were also determined. This chapter further discusses which inclusion criteria with respect to HbA1c and diabetes-related distress would lead to optimal effects of treatment, defined as the number of patients that need to be treated to achieve a successful outcome (Number Needed to Treat (NNT) (52)). The NNT refers to an absolute -as opposed to relative- effect expressed in the number of patients that need to be treated to obtain one successfully treated patient; this outcome is easy to interpret and is directly relevant for clinical practice (53).

Chapter 6 focuses on MIEP's reach and deals with the extent to which patients who have a need for additional diabetes care are recognised in outpatient clinical practice. The 201 patients who took part in MIEP-3 were therefore subdivided into a group of potential candidates for MIEP -according to the physician in attendance- and a group which did not have a need for additional treatment. These two groups were compared to 114 participants from MIEP-2 before these had started MIEP (before they could drop out), but after they had been selected for rehabilitation. This chapter discusses which

patient characteristics (demographic, glycaemic control, diabetes-related distress) influence a physician's decision to consider referral to MIEP. It was also examined whether badly functioning outpatients were overlooked.

Chapter 7 describes the use and effects of telephonic booster sessions for MIEP participants which aimed to keep patients focussed on their diabetes goals after completion of MIEP, thus facilitating the switch from rehabilitation to everyday life. At 3-months follow-up, participants in the MIEP-2 study were therefore randomly assigned to one of two conditions; in one, participants would have four structured telephone conversations with a trained nurse, in the other they would not. In addition, there was a group of patients who did not want to be called but who participated in the study nevertheless. This chapter compares these three groups of patients.

Chapter 8 studies the potentially undermining effect of a spousal context that is incongruous with the empowerment approach advocated in MIEP. The role of overprotection in programme effects in HbA1c, diabetes-related distress and internal locus of control were studied. Patients who perceive their spouse to be rather overprotective were expected to benefit less from MIEP, in terms of an increase in internal locus of control and a decrease in diabetes-related distress and HbA1c, than patients who do not perceive their spouse to behave overprotective. Analyses assessed the independent association of patients' gender, baseline spousal overprotection, and the interaction between gender and spousal overprotection with diabetes self-management at 3-months follow-up, after controlling for the baseline value of the dependent variable.

1.6 References

(1) International Diabetes Federation. Diabetes e-Atlas. http://www.idf.org/e-atlas. 2003.

(2) Rijksintituut voor Volksgezondheid en Milieu (RIVM). Nationaal Kompas Volksgezondheid: Diabetes Mellitus. www.rivm.nl. 2004.

(3) WHO. Defenition, Diagnosis and Classification of Diabetes and its Complications. Geneva: 1999.

(4) World Health Organisation. Prevention of Diabetes Mellitus. Technical Report Series no. 844. 1994. Geneva, WHO.

(5) American Diabetes Association (ADA). Standards of Medical Care for Patients With Diabetes Mellitus. Diabetes Care 24[Supplement 1]. 2001.

(6) Diabetes Control and Complications Trial Research Group. The Effects of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329(14):977-986.

(7) UKPDS. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in

patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. Lancet 1998; 352(9131):837-853.
(8) Diabetes Control and Complications Trial Research Group (DCCT). Influence of intensive diabetes treatment on quality-of-life outcomes in the diabetes control and complications trial. Diabetes Care 1996; 19(3):195-203.
(9) Hahl J, Hamalainen H, Sintonen H, Simell T, Arinen S, Simell O. Health-related quality of life in type 1 diabetes without or with symptoms of long-term complications. Qual Life Res 2002; 11(5):427-436.
(10) Anderson RM, Funnell MM, Carlson A, Saleh-Statin N, Cradock S, Skinner TC. Facilitating Self-care Through Empowerment. In: Snoek FJ, Skinner TC, editors. Psychology in Diabetes Care. Chichester: john Wiley & Sons, LTD, 2000: 69-98.
(11) Jacobson AM. The psychological care of patients with insulin-dependent diabetes mellitus. N Engl J Med 1996; 334(19):1249-1253.
(12) American Association of Diabetes Educators. National Diabetes Education Outcomes System; Intergrating Diabetes Education and Clinical Care; Diabetes Educator's Outcomes Guide Roadmap to Succes. 1-21. 2001.
(13) European IDDM Policy Group. Consensus guidelines for the management of insulin-dependent (type 1) diabetes. European IDDM Policy Group 1993. Diabet Med 1993; 10(10):990-1005.
(14) Banting FG. Diabetes and Insulin: Nobel Lecture. 15-9-1925. Nobel Committee.
(15) Cox DJ, Gonder FL. Major developments in behavioral diabetes research. J Consult Clin Psychol 1992; 60(4):628-638.
(16) Becker MH. The Health Belief Model and Personal Health Behaviour. Health Educ Monogr 1974;(2):324-508.
(17) Fishbein M, Ajzen I. Belief, Attitude, Intention, and Behaviour: an Introduction to Theory and Research. Addision- Wesley: MA, 1975.
(18) Ajzen I. The theory of planned behavior. Organizational Behavior and Human Decision Processes 1991; 50(2):179-211.
(19) Prochaska J, DiClemente C. Stages and processes of self-change of smoking: Toward an integrative model of change. Journal of Consulting and Clinical Psychology 1983; 51(3):390-395.
(20) Glasgow RE, Hampson SE, Strycker LA, Ruggiero L. Personal-model beliefs and social-environmental barriers related to diabetes self-management. Diabetes Care 1997; 20(4):556-561.
(21) Doherthy Y, Hall D, James PT, Roberts SH, Simpson J. Change Counselling in Diabetes: The Development of a Training Programme for the Diabetes Team. Patient Education and Counseling 2000; 40:263-278.
(22) De W, I, Visser AP, Kok G, van d, V. Determinants of active self-care behaviour of insulin treated patients with diabetes: implications for diabetes education. Soc Sci Med 1990; 30(5):605-615.

(23) Doherty Y, Hall D, James PT, Roberts SH, Simpson J. Change counselling in diabetes: the development of a training programme for the diabetes team. Patient Educ Couns 2000; 40(3):263-278.
(24) McNabb WL. Adherence in diabetes: can we define it and can we measure it? Diabetes Care 1997; 20(2):215-218.
(25) Glasgow RE, Osteen VL. Evaluating diabetes education. Are we measuring the most important outcomes? Diabetes Care 1992; 15(10):1423-1432.
(26) Anderson RM, Funnell MM, Barr PA, Dedrick RF, Davis WK. Learning to empower patients. Results of professional education program for diabetes educators. Diabetes Care 1991; 14(7):584-590.
(27) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1995; 18:943-949.
(28) Feste C. A practical look at patient empowerment. Diabetes Care 1992; 15(7):922-925.
(29) Polonsky WH. Diabetes Burnout: What to do when you can't take it anymore. 1 ed. Alexandria: American Diabetes Association, 1999.
(30) Fain JA, Nettles A, Funnell MM, Charron D. Diabetes patient education research: an integrative literature review. Diabetes Educ 1999; 25(6 Suppl):7-15.
(31) Funnell MM, Anderson RM, Arnold MS, Barr PA, Donnelly M, Johnson PD et al. Empowerment: an idea whose time has come in diabetes education. Diabetes Educ 1991; 17(1):37-41.
(32) Coates VE, Boore JR. Knowledge and diabetes self-management. Patient Educ Couns 1996; 29(1):99-108.
(33) Glasgow RE, Fisher EB, Anderson BJ, LaGreca A, Marrero D, Johnson SB et al. Behavioral science in diabetes. Contributions and opportunities. Diabetes Care 1999; 22(5):832-843.
(34) Glasgow RE. Diabetes education research. Diabetes Educ 1999; 25(6 Suppl):5-6.
(35) Anderson RM, Funnell MM. Theory is the cart, vision is the horse: reflections on research in diabetes patient education. Diabetes Educ 1999; 25(6 Suppl):43-51.
(36) Funnell MM. Empowerment: New Role for Health Professionals, New Role for Patients. www.idf.org. 2003.
(37) Keers JC, Blaauwwiekel EE, Hania M, Bouma J, Scholten-Jaegers SMHJ, Sanderman R et al. Diabetes rehabilitation: development and first results of a Multidisciplinary Intensive Education Program for patients with prolonged self-management difficulties. Patient Education and Counseling 2004; 52(2):151-157.
(38) Glasgow RE, Eakin EG, Toobert DJ. How generalizable are the results of diabetes self-management research? The impact of participation and attrition. Diabetes Educ 1996; 22(6):573-2,584.

(39) Snoek FJ, Skinner TC. Psychological counselling in problematic diabetes: does it help? Diabet Med 2002; 19(4):265-273.
(40) Bott U, Bott S, Hemmann D, Berger M. Evaluation of a holistic treatment and teaching programme for patients with Type 1 diabetes who failed to achieve their therapeutic goals under intensified insulin therapy. Diabet Med 2000; 17(9):635-643.
(41) Glasgow RE. A practical model of diabetes management and education. Diabetes Care 1995; 18(1):117-126.
(42) Brown SA. Interventions to promote diabetes self-management: state of the science. Diabetes Educ 1999; 25(6 Suppl):52-61.
(43) Norris SL, Engelgau MM, Narayan KM. Effectiveness of Self-Management Training in Type 2 Diabetes; A Systematic Review of Randomized Controlled Trials. Diabetes Care 2001; 24(3):561-587.
(44) Anderson L. Health-care communication and selected psychosocial correlates of adherence in diabetes management. Diabets Care 1990; 13:66-77.
(45) Bradley C. Clinical trials-time for a paradigm shift? Diabet Med 1988; 5(2):107-109.
(46) Glasgow RE, Eakin EG. Medical Office-based Interventions. In: Snoek FJ, Skinner TC, editors. Psychology in Diabetes Care. Chichester: John Wiley & Sons, 2000: 141-168.
(47) McCulloch DK, Glasgow RE, Hampson SE, Wagner E. A systematic approach to diabetes management in the post-DCCT era. Diabetes Care 1994; 17(7):765-769.
(48) Rubin RR, Peyrot M. Implications of the DCCT. Looking beyond tight control. Diabetes Care 1994; 17(3):235-236.
(49) Cook TD, Campbell DT. Quasi-Experimentation. Design and Analysis Issues for Field Settings. Boston: Houghton Mifflin Company, 1979.
(50) Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health 1999; 89(9):1322-1327.
(51) Diabetes Control and Complications Trial Research Group (DCCT). Lifetime benefits and costs of intensive therapy as practiced in the diabetes control and complications trial. The Diabetes Control and Complications Trial Research Group. JAMA 1996; 276(17):1409-1415.
(52) Laupacis A, Sackett DL, Roberts RS. An assessment of clinically useful measures of the consequences of treatment. N Engl J Med 1988; 318(26):1728-1733.
(53) Cook RJ, Sackett DL. The number needed to treat: a clinically useful measure of treatment effect. BMJ 1995; 310(6977):452-454.

2

Diabetes rehabilitation: Development and first results of a Multidisciplinary Intensive Education Programme for patients with prolonged self-management difficulties.

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Abstract

Introduction
For a number of diabetes patients regular care may be insufficient. A Multidisciplinary Intensive Education Programme (MIEP), based on the empowerment approach, has been developed to help patients obtain their treatment goals (adequate self-management, glycaemic control and quality of life). The aim of this pilot study is to determine the effects of MIEP and it's mechanisms of influence.

Methods
MIEP consisted of 12 days group-sessions and individual counselling. At baseline and 3-months follow-up, blood-glucose (HbA1c), quality of life, health locus of control, distress, and knowledge were obtained (N=51). Paired T-tests and regression analyses were conducted.

Results
HbA1c and knowledge improved significantly, patients rated themselves healthier and were more *internal* and less *powerful others* oriented. Baseline scores explained effects in HbA1c and quality of life. Locus of control significantly contributed in effects on quality of life.

Conclusions
MIEP benefited patients with prolonged self-management difficulties, and this form of care seems to complement regular care.

2.1 Introduction

Diabetes Mellitus is a growing public health issue (1), which can cause serious disabling complications. Risks of developing these complications can be significantly reduced by optimal glycaemic control (2), which is the maintenance of low blood-glucose near levels found in persons without diabetes (3;4). Optimal glycaemic control can be achieved by correct and conscientious self-management (5), which consists of home blood glucose monitoring, injecting insulin and adjusting the insulin dose to actual needs, varying nutrition to daily needs and regular exercise (6;7). However, diabetes self-management is demanding and requires much effort, discipline, skill and knowledge. Not surprisingly, a considerable number of patients never reaches optimal glycaemic control (8); less then 15% has normal or near normal glycaemic control and about 25% has poor control (2;9). Besides sub-optimal glycaemic control, several studies found that a considerable number of patients experience diabetes-related psychosocial problems (10;11).

Diabetes education is considered to be essential in reaching good self-management and glycaemic control (12-14). Usually, the aim is to increase knowledge of self-management principles and self-management skills in order to achieve sufficient glycaemic control. A meta-analysis (15) showed that education programmes increase knowledge about diabetes mellitus, but have moderate effects on glycaemic control and even smaller effect on psychological outcomes. Most diabetes education programmes primarily focus on knowledge and glycaemic control, while psychological aspects and determinants of self-management behaviour, such as coping with diabetes and health locus of control receive less attention (16). Usually, a lack of knowledge is not the main issue (17), but rather a variety of problems that contribute to prolonged self-management difficulties (18). Besides a focus on knowledge and self-management skills to achieve satisfying glycaemic control, health-related quality of life should be a matter of concern in treatment of diabetes education (16;19;20).

Based on the patient empowerment approach (21), a Multidisciplinary Intensive Education Programme (MIEP) was developed (see 2.2.2). MIEP focuses on patients with continued poor regulation and/or psychosocial problems related to diabetes, despite intensive regular care. This paper describes the development and effects of MIEP examined in a pilot study in 51 participants. The aim of this study is to determine the effects of this newly developed form of diabetes education on glycaemic control and quality of life and to gain insight into the mechanisms of effect.

2.1.1 Empowerment

The empowerment approach to diabetes-education (21) involves a great amount of patient collaboration. The patient empowerment approach seeks to

maximize self-awareness and a sense of personal autonomy, which enable patients to take charge of their own diabetes self-management (22).

Anderson et al. (22) mentioned three aspects of diabetes treatment that argue in favour of the empowerment approach in diabetes education. First, the most important choices affecting the patient's health and well-being are made by the person suffering from diabetes him/herself, not by educators or physicians. The choices the patient makes each day about his or her self-management, cumulatively, have a far greater impact on blood glucose levels, overall health and well-being than the decisions made and advise given by health care providers. Second, patients are in control of their diabetes self-management; no matter what health providers recommend patients can veto any recommendation. Third, the consequences of a patient's choices about diabetes care accrue first and foremost to patients themselves.

Education based on patient empowerment should focus on achievement of self-selected goals, psychosocial adaptation, enhanced control (22), and problem solving strategies (23). Empowerment can be more effective in attaining patient-oriented and medical outcomes (24;25).

2.1.3 Programme

Figure 1 gives an overview of the programme. MIEP consists of a core module of 5 weeks consisting of 2 days a week (from MIEP-1 on changed to one day a week for 10 weeks) filled with group sessions and individual counselling. Subsequently, MIEP includes revisits after 6 and 12 weeks. Groups comprise 6 to 9 patients. The diabetes education team consists of an internist, a diabetes nurse specialist, a nutritionist, a social worker, a psychologist, a physiotherapist, an occupational therapist, an activity therapist and a podiatrist. The diabetes nurse specialist co-ordinates the programme.

The programme highlights a wide variety of subjects related to diabetes self-management (see Figure 1). These issues are subjects during several sessions throughout the programme. The programme applies a four-phase learning sequence that integrates learning and practice. In the first phase, patients receive information from a team member about one of the issues mentioned, in the second phase followed by group discussions or practice. In the third phase of the sequence, patients set goals and plan how to practice a certain issue at home. In the fourth phase practice at home is evaluated. This four-phase learning sequence is repeated for different aspects of diabetes self-management, tailored to the issue at hand. Not only do team members provide activities separately, as disciplines work together combinations of issues are made in co-operative sessions.

Before patients enter the programme, they set personal goals, which could become more specified during the ten-week programme. Frequently mentioned personal goals were lowering HbA1c or improving glycaemic

control. Further personal goals were the avoidance of hypoglycaemia, obtaining a higher level of self-direction in self-management, the acceptance of diabetes and establishing a greater ability to combine diabetes and other activities. Patients receive individual counselling tailored to their personal goals to help them reach their goals.

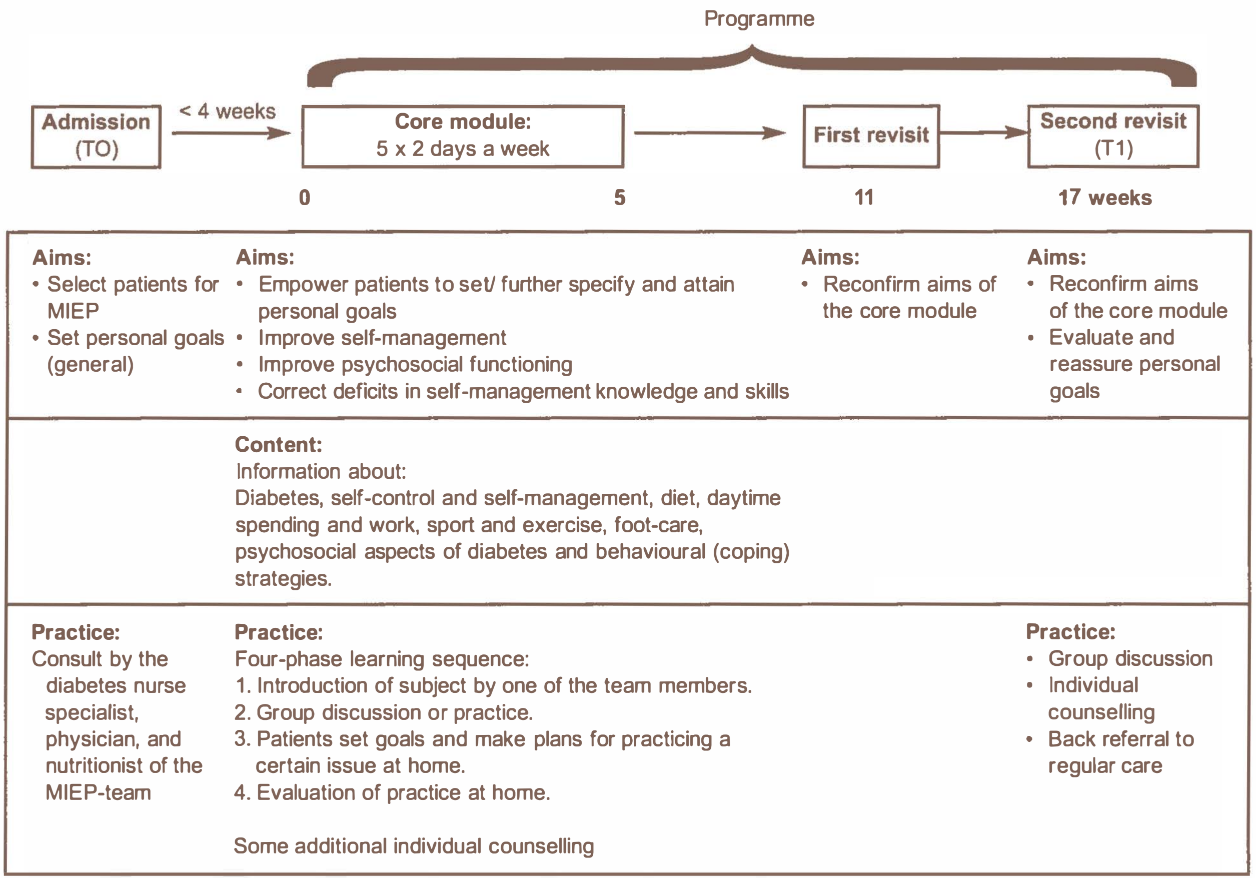

Figure 1: Multidisciplinary Intensive Education Programme (MIEP)

2.2 Methods

2.2.1 Patients

Patients, monitored at the diabetes clinic of the University Hospital Groningen, were included on basis of the following criteria: sub-optimal glycaemic control (HbA1c > 7.5 %) for at least one year and/or frequent or severe hypoglycaemia and/or psychosocial limitations resulting from diabetes. In contrast to inclusion based on the level of HbA1c, inclusion based on hypoglycaemia and psychosocial problems was not strictly defined. Rather, these criteria were verified by the referring physician and during an interview on admission to MIEP. Exclusion criteria were age <18 or >70 years, severe co-morbidity or a severe major life-event during the 6 months preceding MIEP. All patients had received conventional care for at least one year without improvement in HbA1c, hypoglycaemia and psychosocial problems. Selection of patients was based on medical reports and on the admission interview. After having finished the programme, which took place in the rehabilitation centre, patients were referred back to their own physician in the university hospital.

2.2.3 Design

A longitudinal pre-test-post-test design was used. A pre-measurement (T0) was done at admission, before patients entered MIEP. At the second revisit, which is also the last day of the programme, a post-measurement (T1) was obtained.

2.2.4 Measurements

The primary outcome variables of the study were glycaemic control (HbA1c) and quality of life. The secondary outcome variables were diabetes-related symptoms (except the sub-scale of cognitive distress) and the number of (severe) hypoglycaemia occurrences. Several process variables (cognitive distress, health locus of control and knowledge) were measured as well.

Glycaemic control was measured by glycosylated haemoglobin (HbA1c) indicating the mean blood-glucose levels over the previous 6-8 weeks. Patients with diabetes should strive for HbA1c values near normal (as in healthy individuals/ <7.0%) (7), since an elevated HbA1clevel is strongly related to the development of complications (2). The self-reported number of hypoglycaemia in the previous four weeks as well as severe hypoglycaemia for which assistance was required was obtained.

Quality of life was measured with the RAND-36 (26;27). The RAND-36 consists of 9 sub-scales of which 6 were used in this study: physical functioning, social functioning, mental functioning, vitality, general health

perception and health change. Each scale is transformed to a 100-point scale with 0 representing the lowest possible quality of life and 100 representing the highest possible quality of life.

Diabetes related symptoms were measured with the Diabetes Symptom Checklist (DSC) developed by Grootenhuis et al. (28). The DSC measures symptoms of diabetes complications. It consists of eight sub-scales: hyperglycaemia (5 items; range 0-15), hypoglycaemia (3 items; range 0-9), cardiovascular (4 items; range 0-12), neuropathy-pain (6 items; range 0-18), neuropathy-sensory symptoms (4 items; range 0-12), fatigue (4 items; range 0-12), ophthalmic symptoms (5 items; range 0-15) and cognitive distress (4 items; range 0-12). A low score represents few symptoms and a high score represents a lot of symptoms. In contrast to the seven other sub-scales of the DSC, the cognitive distress represents a psychological state and was used as a process variable.

The Dutch version of the health locus of control scale of Wallston, Wallston and DeVellis (29), for diabetes patients, was used (30). The MHLC includes three sub-scales: *Internal* (i.e. control depends on own effort), *Powerful Others* (i.e. control depends on others such as the physician) and *Chance* (i.e. control depends on luck or chance). Each scale consists of 6 items. The range of each scale varies from 6 to 36, where a high score represents a stronger orientation on the specific locus of control.

A revised version of the Diabetes Knowledge Scale (DKS) (31;32) was used to measure knowledge. This scale consists of 30 items, which were summed (range: 0-30) with higher scores indicating better diabetes knowledge.

2.2.5 Statistics

The statistical package SPSS/PC+ for Windows was used. To determine differences between pre- and post-measure paired T-Tests were used ($p < .05$). To investigate the mechanisms of effect stepwise regression analysis were applied. The behavioural determinants (MHLC, knowledge, cognitive distress) were used as independent variables. Health related quality of life and HbA1c were dependent variables in these analyses. Age, sex and the baseline value of the outcome variable were controlled for. The criteria used were a probability of F to enter $\leq .05$ and probability of F to remove $\geq .10$.

2.3 Results

2.3.1 Patients

Out of the 58 patients that were eligible for the education programme, 51 were evaluated. Seven patients (3 male, 4 female) did not complete the

programme and were excluded from the study. Two of these patients quit because of hearing problems that made participation in group-sessions impossible, and five discontinued the programme because of motivational reasons. Table 1 shows the characteristics at baseline of the included patients.

Table 1: Patient Characteristics

Gender*	Male	25 (49%)
	Female	26 (51%)
Educational level*	Primary school	19 (37%)
	Lower secondary vocational school	13 (26%)
	Higher secondary vocational school	16 (31%)
	Pre-university school	3 (6%)
Age†		49.10 (15.15)
HbA1c (%)†		8.14 (1.31)
BMI†		29.14 (6.62)

* Number (percentage) of patients of gender and education
† Mean (SD) of age, HbA1c and BMI

2.3.2 Outcomes of the programme

Table 2 shows that patients significantly improved their glycaemic control: mean HbA1c declined from 8.14 (1.31) at T0 to 7.75 (1.11) at T1. Change in HbA1c correlated -.58 ($p < .001$) with HbA1c at T0, indicating that patients with worst glycaemic control improved most. Fifty percent of the patients showed a clinical relevant improvement of at least .5% HbA1c, while, on the other hand, 18% of the patients worsened ≥.5 on HbA1c. The other 32 % of the patients remained relatively stable (14 % <.5 improvement, 12% <.5 deterioration and 6% no change at all). Overall, no change in the number of hypoglycaemia in a four-week period was found. However, change in HbA1c (T1-T0) correlated significantly ($r = -.46$; $p<.01$) with change in number of hypoglycaemia, indicating that patients that improved most in HbA1c experienced more hypoglycaemia, whereas patients that improved less in HbA1c showed less hypoglycaemia. Most patients (84%) reported both at T0 and at T1 that they had not experienced any severe hypoglycaemia for which help was required. Four (8%) patients who had one to three severe hypoglycaemia reported none at T1, two patients (4%) required five and six times assistance, improved to three and two times help respectively. One patient (2%) had one severe hypoglycaemic period at both times, and one patient (2%) who had none at T0, needed help three times at T1.

Health change was the only quality of life sub-scale on which patients improved significantly. At baseline patients scored 46.87 (22.92) (patients indicated their health slightly worse than a year ago), 3 months after treatment patients scored 59.89 ($t = 3.71$; $p < .01$). At T1, 44% of the patients indicated their health to be better than one year earlier, and 46% of the patients indicated that their health was about the same as before, while 10% reported their health had deteriorated during the past year.

No significant changes on self-reported symptoms on the Diabetes Symptom Checklist were found, although on most sub-scales, small improvements were found and relatively little patients worsened.

Table 2: Programme outcomes

	T0	T1	t
Metabolic control:			
HbA1c	8.14 (1.31)	7.75 (1.11)	2.40*
N 0f hypoglycemia (4 weeks)	4.06 (6.40)	4.21 (4.71)	-.16
% self-testing for blood glucose	94%	100%	-
Quality of life and health status:			
Physical functioning	77.75 (24.91)	74.79 (25.11)	-1.02
Social functioning	74.02 (21.19)	79.17 (18.65)	1.73
Mental functioning	71.06 (17.28)	70.58 (15.82)	-.47
General health perception	52.65 (17.53)	52.60 (17.59)	-.29
Health change	46.87 (22.92)	59.89 (26.16)	3.71**
Self-reported symptoms:			
Headache	3.14 (3.16)	3.19 (2.83)	.00
Hyperglycaemia	1.68 (1.71)	1.28 (1.50)	-1.78
Hypoglycaemia	2.80 (2.56)	2.31 (2.18)	-1.55
Cardiovascular complaints	1.58 (1.92)	1.42 (1.90)	-.85
Pain	1.37 (2.14)	1.20 (2.03)	-.72
Neurological complaints	2.14 (2.44)	1.96 (2.35)	-.67
Fatigue	4.05 (3.12)	3.52 (2.71)	-1.61
Visual complaints	1.82 (2.14)	1.53 (2.26)	-1.16
Process and mediating variables:			
Health locus of control:			
Internal	22.79 (3.63)	23.87 (3.96)	2.15*
Powerful others	19.40 (4.45)	18.23 (4.05)	-2.06*
Chance	18.57 (3.63)	17.87 (3.19)	-1.26
Cognitive distress	3.04 (2.30)	2.66 (2.02)	-1.53
Knowledge	20.22 (4.85)	22.93 (3.38)	4.94**

* $p < .05$ ** $p < .01$

Table 3: Outcomes of regression analyses† on changes in HbA1c and quality of life

		R^2	F	Beta
Change in HbA1c (T1 - T0)		.32	21.34***	
Predictor:	HbA1c T0			.57***
Change in quality of life (T1 - T0)				
Physical functioning		.29	5.82**	
Predictors:	age			-.30*
	physical functioning T0			-.41**
	Chance health locus of control (T1 - T0)			-.33*
Social functioning		.48	40.90***	
Predictor:	social functioning T0			-.69***
Mental functioning:		.21	11.58**	
Predictor:	mental functioning T0			-.45**
General health perception				
Predictor:	no predictors			
Health change:		.27	8.27**	
Predictors:	health change T0			-.48**
	internal health locus of control (T2-T0)			.31*

* $p < .05$
** $p < .01$
***$p<.001$
†Method: stepwise
Criteria: Probability of F to enter <= .050, probability of F to remove >= .100
Independent variables inserted in analyses: baseline (T0) measure of the dependent variable, age, gender, change in health locus of control, knowledge and cognitive distress.

2.3.3 Mechanisms of effect

To gain insight into mechanisms of effect of MIEP, several determinants of self-management were measured. At follow-up patients had a more *internal* locus of control and less *powerful others* locus of control (see Table 2). Patients also improved on the diabetes knowledge test ($t = 4.94$; $p < .01$). No significant decrease in cognitive distress was found ($t = -1.53$, ns).

To investigate the role of the process variables in outcome variables stepwise regression analyses were conducted. Table 3 shows that HbA_{1c} after treatment is partly explained by HbA1c before treatment. People with relative high HbA_{1c} at T0 improved most. None of the process variables significantly adds variance to this analysis.

Most changes in quality of life aspects were predicted by their baseline values: lower baseline scores are related to greater improvement, meaning that patients with the highest need for improvement show the greatest effect. Changes in physical functioning and health change were predicted by other variables as well (see table 3). Change in physical functioning was predicted by age, physical functioning at baseline and *change* in chance health locus of control respectively. Elderly patients and patients with high initial physical functioning improved relatively little, while patients with the largest reduction in health locus of control increased relatively more in physical functioning. Change in health change is predicted by respectively health change at baseline, and by change in *internal* health locus of control. Patients who increased most in *internal* health locus of control reported a relative greater improvement in health change. Although knowledge improved significantly, this did not contribute in mechanisms of effect.

2.4 Discussion and conclusion

This study indicates that the Multidisciplinary Intensive Education Programme has shown beneficial effects on glycaemic control. In the group as a whole, HbA1c improved significantly. Patients with worst control at baseline improved most, and half of the patients showed a clinically relevant decline in HbA1c. The number of hypoglycaemia did not diminish, most likely due to the fact that tighter glycaemic regulation is related to an increase in hypoglycaemia (5;33-36). However, the number of severe hypoglycaemia did not increase and the few patients that experienced severe hypoglycaemia at baseline improved considerably in this respect.

2.4.1 Discussion

Limited changes in health related quality of life were found, which may be both explained by applying a general quality of life measure and the selection of patients. MIEP is aimed at a specific group of diabetes patients with poor glycaemic control and psychosocial limitations resulting from diabetes, but without major co-morbidity (exclusion criterion). Several studies indicate that diabetes does not have a great impact on general quality of life, but that complications do (5;33-36). At baseline of MIEP, participants already reported a rather good quality of life with scores over 70 on most Rand-36 sub-scales. However, patients referred to MIEP are at risk of developing diabetes-related co-morbidity, which will affect overall quality of life (37). To detect the diabetes related psychosocial problems in the participants of MIEP a more disease-specific quality of life measure will probably shed some more light on the effects on health-related quality of life. The question remains whether patients with the highest need for diabetes rehabilitation, that is with complex

problems, were referred and selected adequately. To better reach this potential group of patients, referring physicians, who likely mainly focus on glycaemic control, should be better informed about this new form of diabetes education and its target population.

In many cases traditional diabetes education is foremost oriented at knowledge (9;17;32), although other variables might be more important to focus on. The results show that patients had a higher level of knowledge after treatment and were more *internal* and less *powerful others* oriented. Health locus of control can be regarded as an indicator of the concept of empowerment. Empowered patients should be mainly *internal* oriented and have a low *powerful others* and *chance* orientation. According to the changes in HLOC patients became more empowered after MIEP. Health locus of control was a determinant of programme-effects; patients who became less *chance* oriented reported an increase in physical functioning and patients who became more *internal* oriented considered their health better to be than a year before.

Interestingly, analyses did not indicate knowledge as a determinant of outcomes of the treatment, supporting research that showed the limited effects of improving knowledge in advanced education (32). To analyze mechanisms of effect more accurately, a greater group of patients is needed and a wider variety of behavioural determinants should be measured.

The group of patients that participated in MIEP was rather heterogeneous with respect to age, glycaemic control and quality of life. It is reasonable to assume that personal goals of patients will diverge on these aspects, too. In regression analyses on programme-effects baseline scores were controlled for, and had an effect in all regression analyses except for general health perception. That is, patients with worst glycaemic control, health change, physical, social or mental functioning at baseline improved relatively more on the outcome concerned. Subgroup analysis might therefore be preferable, but the present study included too small a number of patients to elaborate on this idea.

Practical limitations of the study made it impossible to conduct a randomized trial, which leaves room for alternative explanations for effects. Patients who were referred to MIEP had poor glycaemic control or limitations for at least one year despite intensive regular care. That is, patients already received extra attention for their diabetes, which makes it implausible that effects of MIEP are only due to simply giving attention. Furthermore, data were collected 12 weeks after the core module of treatment, when possible effects of just giving attention would have disappeared.

This study indicates that tailored intensive diabetes self-management education for patients who profit unsatisfactorily from intensive regular care, contributes significantly to improvement in HbA1c, prevention of severe hypoglycaemia and to a lesser extent to general health-related quality of life. More research is needed to specify the group of patients who primarily

benefit from such a programme, and to better clarify the mechanisms of effect involved in diabetes education. The mere knowledge that the programme is effective is not enough, to find out how it works (mechanisms of effect) may be even more important. For example, what is the role of behavioural determinants we studied? To determine stability of effects over time patients have to be monitored for a longer period after treatment.

2.4.2 Practice implications

For patients who failed to achieve their treatment goals under prolonged intensive regular care, intensive education programmes might be beneficial, although the selection procedure of patients and the measurement of effects need more attention. Diabetes treatment largely involves patients' own efforts and it forces patients to make informed decisions each day, which makes patient centred education, as in the empowerment approach, the preferable form of education. Especially patients with poor glycaemic control (HbA1c) should be referred to programmes like MIEP, since several studies showed a strong relation between improved glycaemic control and reduced risks of developing complications (2;38). It is important to measure psychological distress and process variables accurately, with disease-specific measures, to determine effects of diabetes education in this respect and be able to optimise treatment.

2.5 References

(1) Mandrup PT. Diabetes. BMJ 1998; 316(7139):1221-1225.

(2) Diabetes Control and Complications Trial Research Group. The Effects of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329(14):977-986.

(3) Diabetes Control and Complications Trial Research Group (DCCT). Lifetime benefits and costs of intensive therapy as practiced in the diabetes control and complications trial. The Diabetes Control and Complications Trial Research Group. JAMA 1996; 276(17):1409-1415.

(4) UKPDS. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. Lancet 1998; 352(9131):837-853.

(5) Diabetes Control and Complications Trial Research Group (DCCT). Influence of intensive diabetes treatment on quality-of-life outcomes in the diabetes control and complications trial. Diabetes Care 1996; 19(3):195-203.

(6) Aalto AM, Uutela A, Aro AR. Health related quality of life among insulin-dependent diabetics: disease-related and psychosocial correlates. Patient Educ Couns 1997; 30(3):215-225.
(7) American Diabetes Association (ADA). Standards of Medical Care for Patients With Diabetes Mellitus. Diabetes Care 24[Supplement 1]. 2001.
(8) Goddijn PP, Bilo HJ, Feskens EJ, Groeniert KH, van-der-Zee KI, Meyboom-de JB. Longitudinal study on glycaemic control and quality of life in patients with Type 2 diabetes mellitus referred for intensified control. Diabet Med 1999; 16(1):23-30.
(9) Dalewitz J, Khan N, Hershey CO. Barriers to control of blood glucose in diabetes mellitus. Am J Med Qual 2000; 15(1):16-25.
(10) Jacobson AM. The psychological care of patients with insulin-dependent diabetes mellitus. N Engl J Med 1996; 334(19):1249-1253.
(11) Rubin RR, Peyrot M. Psychosocial problems and interventions in diabetes. A review of the literature. Diabetes Care 1992; 15(11):1640-1657.
(12) Peyrot M, Rubin RR. Modeling the effect of diabetes education on glycemic control. Diabetes Educ 1994; 20(2):143-148.
(13) Muhlhauser I, Overmann H, Bender R, Bott U, Jorgens V, Trautner C et al. Social status and the quality of care for adult people with type I (insulin-dependent) diabetes mellitus--a population-based study. Diabetologia 1998; 41(10):1139-1150.
(14) Berger M, Muhlhauser I. Diabetes care and patient-oriented outcomes. JAMA 1999; 281(18):1676-1678.
(15) UKPDS. Quality of life in type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control (UKPDS 37). U.K. Prospective Diabetes Study Group. Diabetes Care 1998; 22:1125-1136.
(16) Glasgow RE, Osteen VL. Evaluating diabetes education. Are we measuring the most important outcomes? Diabetes Care 1992; 15(10):1423-1432.
(17) Coates VE, Boore JR. Knowledge and diabetes self-management. Patient Educ Couns 1996; 29(1):99-108.
(18) Schwartz LS, Coulson LR, Toovy D, Lyons JS, Flaherty JA. A biopsychosocial treatment approach to the management of diabetes mellitus. Gen Hosp Psychiatry 1991; 13(1):19-26.
(19) Rubin RR, Peyrot M. Quality of life and diabetes. Diabetes Metab Res Rev 1999; 15:205-218.
(20) Rose M, Fliege H, Hildebrandt M, Schirop T, Klapp B. The network of psychological variables in patients with diabetes and their importance for quality of life and metabolic control. Diabetes Care 2002; 25(1):35-42.
(21) Funnell MM, Anderson RM, Arnold MS, Barr PA, Donnelly M, Johnson PD et al. Empowerment: an idea whose time has come in diabetes education. Diabetes Educ 1991; 17(1):37-41.

(22) Anderson RM, Funnell MM, Carlson A, Saleh-Statin N, Cradock S, Skinner TC. Facilitating Self-care Through Empowerment. In: Snoek FJ, Skinner TC, editors. Psychology in Diabetes Care. Chichester: John Wiley & Sons, LTD, 2000: 69-98.
(23) Anderson RM, Funnell MM. Theory is the cart, vision is the horse: reflections on research in diabetes patient education. Diabetes Educ 1999; 25(6 Suppl):43-51.
(24) Norris SL, Engelgau MM, Narayan KM. Effectiveness of Self-Management Training in Type 2 Diabetes; A Systematic Review of Randomized Controlled Trials. Diabetes Care 2001; 24(3):561-587.
(25) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1995; 18:943-949.
(26) Ware JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36) : I. Conceptual framework and item selection. Med Care 1992; 30(6):473-483.
(27) Van der Zee K, Sanderman R, Heyink JW, De Haes H. Psychometric qualities of the RAND 36-item Health Survey 1.0: a multidimensional measure of general health status. Int J Behav Med 1996; 3(2):104-122.
(28) Grootenhuis PA, Snoek FJ, Heine RJ, Bouter LM. Development of a type 2 diabetes symptom checklist: a measure of symptom severity. Diabet Med 1994; 11(3):253-261.
(29) Wallston KA, Wallston BS, DeVellis R. Development of the Multidimensional Health Locus of Control (MHLC) Scales. Health Educ Monogr 1978; 6(2):160-170.
(30) Halfens R. Locus of Control:De beheersingsorientatie in relatie tot ziekte- en gezondheidsgedrag. Limburg University, 1985.
(31) Dunn SM, Bryson JM, Hoskins PL, Alford JB, Handelsman DJ, Turtle JR. Development of the diabetes knowledge (DKN) scales: forms DKNA, DKNB, and DKNC. Diabetes Care 1984; 7(1):36-41.
(32) Dunn SM, Beeney LJ, Hoskins PL, Turtle JR. Knowledge and attitude change as predictors of metabolic improvement in diabetes education. Soc Sci Med 1990; 31(10):1135-1141.
(33) Nerenz DR, Repasky DP, Whitehouse FW, Kahkonen DM. Ongoing assessment of health status in patients with diabetes mellitus. Med Care 1992; 30(5 Suppl):MS112-MS124.
(34) Hanestad BR. Self-reported quality of life and the effect of different clinical and demographic characteristics in people with type 1 diabetes. Diabetes Res Clin Pract 1993; 19(2):139-149.
(35) De-Sonnaville JJ, Snoek FJ, Colly LP, Deville W, Wijkel D, Heine RJ. Well-being and symptoms in relation to insulin therapy in type 2 diabetes. Diabetes Care 1998; 21(6):919-924.

(36) De-Grauw WJ, van-de-Lisdonk EH, Behr RR, van-Gerwen WH, van-den-Hoogen HJ, van-Weel C. The impact of type 2 diabetes mellitus on daily functioning. Fam Pract 1999; 16(2):133-139.
(37) Meijer JWG, Trip J, Jaegers SMHJ, Links TP, Smits AJ, Groothoff JW et al. Quality of Life in Patients with Diabetic Foot Ulcers. Disability and Rehabilitation 2001; 23(8):336-340.
(38) UKPDS. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). UK Prospective Diabetes Study (UKPDS) Group [see comments] [published erratum appears in Lancet 1998 Nov 7;352(9139):1557]. Lancet 1998; 352(9131):854-865.

3

Diabetes rehabilitation: Effects of a Multidisciplinary Intensive Education Programme for diabetic patients with prolonged self-management difficulties

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Submitted

Abstract

Objectives
This study aimed to determine effects of a Multidisciplinary Intensive Education Programme (MIEP) based on the empowerment approach for diabetic patients with prolonged self-management difficulties.

Methods
In 89 participants, glycaemic control (HbA1c), health related quality of life (HR-QoL) and indicators of empowerment were measured before MIEP (10 days in 10 weeks, follow-up after 6 and 12 weeks) and at 12 weeks follow-up. The participants were compared with 231 non-referred, average outpatients who were measured once. Since participants pursued different treatment goals, subgroups with poor and satisfactory HbA1c and mental health were distinguished.

Results
Overall, participants improved their glycaemic control, mental health, satisfaction with treatment and became more empowered. Post-treatment, participants and outpatients hardly differed anymore. Subgroup-analyses revealed that especially patients with poor baseline control improved their HbA1c. At baseline, participants with poor mental health scored worse on all other HR-QoL subscales too and were less empowered compared to the satisfactory mental health group. The poor mental health participants improved in most of these aspects and differences between the subgroups became smaller.

Conclusions
MIEP has beneficial effects in HbA1c, HR-QoL, and empowerment, especially in patients with poor status at baseline. MIEP holds promise for patients with prolonged self-management difficulties, that could inadequately be treated in intensive regular care.

3.1 Introduction

Diabetes can have seriously disabling complications. The risks of developing diabetic complications can be significantly reduced by optimising glycaemic control (1;2) Correct and conscientious self-management is the key to obtain satisfactory glycaemic control (3). Self-management consists of correct medication (insulin) use, a healthy diet and sufficient physical exercise, and most importantly balancing these elements accordingly daily requirements. (2;4) Besides good glycaemic control, an important goal of diabetes treatment is to enable patients to obtain and maintain good health related quality of life (HR-QoL) (3;5).

Diabetes self-management is complicated, and demands much effort, discipline and skills. Not surprisingly, therefore, a considerable number of patients has difficulties with self-management (6), which shows in poor glycaemic control (7;8), psychosocial problems and reduced HR-QoL (9-15). Diabetes education is considered crucial in providing patients with sufficient resources for effective self-management (16). Conventional diabetes education programmes primarily focus on improving knowledge in order to improve glycaemic control (17;18). However, to optimise diabetes treatment it is important to consider patient-oriented outcomes such as HR-QoL as well (5;19). Furthermore, traditional education pays little attention to behavioural determinants of self-management (19-21). Education that involves patient collaboration, as in the empowerment approach (22), can be more effective in attaining patient-oriented and medical outcomes (19).

Few diabetes education programmes explicitly focus on patients with self-management difficulties (23), although such programmes have had positive outcomes. Intensive, patient-oriented education might be particularly important for these patients. Fosbury (24) developed a focused, time-limited cognitive analytic therapy for poorly controlled type-1 patients, which resulted in improved glycaemic control and knowledge and fewer interpersonal problems. Snoek et al. (25) developed a cognitive-behavioural group training for poorly controlled patients, which resulted in improved glycaemic control, reduced diabetes-related distress and improved well-being (26). A holistic education programme for diabetes patients who failed to achieve their therapeutic goals led to a reduction in severe hypoglycaemia, and improved self-efficacy (27).

Combining these elements that contribute to the effectiveness of intensive diabetes interventions, we developed a diabetes rehabilitation programme *(Multidisciplinary Intensive Education Programme; MIEP)* (28). The aim of the present study is to determine the effects of this programme. MIEP is intended for patients with prolonged self-management difficulties despite intensive regular care. In the Netherlands, regular care for all type 1 patients and for type 2 patients with poor control or diabetes complications consists of four annual consultations by a diabetologist and if necessary consultation by

a diabetes nurse specialist, a dietician, and a podiatrist. MIEP aims at patients who, despite intensive regular care and optimised medical treatment, did not reach their treatment goals. Participants in MIEP were selected on prolonged poor glycaemic control and psychosocial problems related to diabetes self-management.

The aim of this study is to determine effects of MIEP. To put effects into perspective we compared the treatment group with non-referred consecutive outpatients before and after MIEP. The latter group can be considered as average diabetic patients. However, only considering overall outcomes would ignore that patients pursue different treatment goals. The need for improvement in outcomes probably varies between sub-groups of patients. In order to meet the aim of this study, sub-groups of patients will be distinguished with respect to two common areas of treatment goals: improving glycaemic control and improving mental health.

3.2 Methods

3.2.1 Patients and Procedure

Participants of MIEP

MIEP was conducted in Centre for Rehabilitation Beatrixoord, University Hospital Groningen, the Netherlands. Patients were referred to the programme from diabetes outpatient clinics in the region. Inclusion criteria were having poor glycaemic control and/or frequent hypoglycaemia and/or diabetes-related psychosocial problems, for a period of at least a year without improvement. Patients younger than 18 or over 75, patients with severe co-morbidity (physically and mentally), or a poor command of the Dutch language were excluded. The internist, diabetes nurse specialist, dietician and the psychologist of the MIEP education-team interviewed the patients on admission to determine whether patients could be included in MIEP.

All patients who participated in MIEP were approached for this study. One hundred and nineteen patients entered the programme and were eligible for this study. After admission, 13 patients discontinued MIEP for motivational reasons, one patient died and 16 patients completed the programme but failed to return the (completed) questionnaire at follow-up (non-response). The final research sample comprised thus 89 patients. No significant differences in age, type of diabetes baseline HbA1c, or baseline mental health were found between participants (N = 89) and non-participants (N = 30).

Patients were measured at baseline before they enrolled into the programme (T0), and 22 weeks later at the second follow-up visit (= end of the programme; T1) (see Figure 1). Two HbA1c values, measured in the year previous to MIEP and determined in the same laboratory that determined HbA1c in MIEP, were available from the 37 patients who were referred from the University Hospital Groningen.

Reference group
Using the same exclusion criteria as MIEP, we selected 330 consecutive non-referred outpatients from the diabetes clinic of the Groningen Unversity Hospital to serve as a reference group. These patients could be considered average outpatient diabetic patients. After informed consent, 231 patients (70.0%) took part in the study, completed the questionnaire and gave permission to obtain their most recent HbA1c value. This reference group was only measured once.

3.2.2 Programme

MIEP is based on the empowerment approach (22), which aims to empower patients to set and attain their own treatment goals, and involves patients to a strong degree in their own treatment (29;30). The patient empowerment approach asserts that diabetes patients make choices each day that affect and are affected by their emotions, goals, and other psychosocial determinants of living with diabetes (31;32). Some elements of traditional education are integrated in MIEP as well, because empowerment and diabetes patient education are complementary (33).

MIEP comprised ten one-day-a-week group sessions and some individual support. Every patient received about the same amount of individual support given by the healthcare provider(s) that could best treat patients' individual needs. Follow-up visits were scheduled 6 and 12 weeks after the ten-week block (see Figure 1). Groups comprised 6 to 9 patients. The diabetes education team consisted of a diabetes nurse specialist (programme co-ordinator), an internist, a nutritionist, a social worker, a psychologist, a physiotherapist, an occupational therapist and an activity therapist. MIEP was embedded in a rehabilitation clinic, which made it possible to work with such a multidisciplinary education team in an intensive way and to use several facilities (such as sports accommodations).

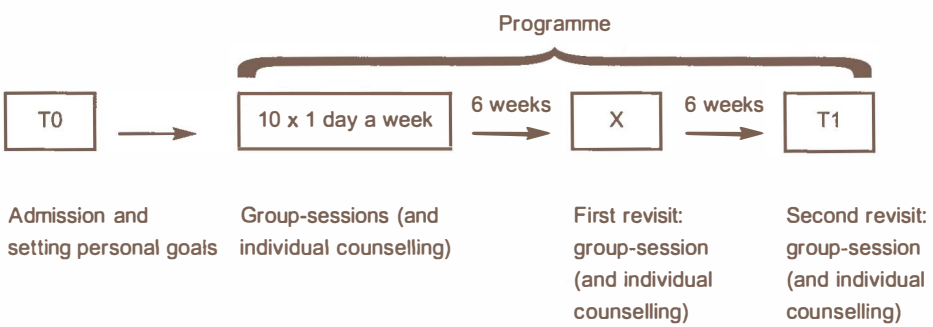

Figure 1: Programme design of MIEP

The programme highlighted a range of topics related to diabetes self-management. MIEP has modules on self-management, diet, exercise, daily routine and employment, and psychosocial aspects of diabetes and behavioural (coping) strategies. The programme used a four-phase learning sequence. First, a topic was introduced, followed by group discussion or practice. In the third phase, patients set goals, planned how to practise a certain aspect at home and how to fit it in their lives, which was subsequently evaluated in the fourth phase. In this four-phase learning sequence, combining learning and experiencing, combinations of diabetes self-management aspects were made in interactive sessions. The contents of all modules were based on patients' own experiences and goals, which made the treatment personally relevant and made it possible for patients to learn from each other. Education directed solely at patient priorities does carry the risk that essential aspects of diabetes self-management and care are left out (34). By providing an educational framework in MIEP, we ensured that these essential aspects of diabetes education were covered. To help patients to achieve their personal goals, team members provided some individual treatment.

3.2.3 Measurements

In diabetes care and research, the most common way to determine glycaemic control is by means of glycated haemoglobin (HbA1c). HbA1c gives an indication of glucose control in the past six to eight weeks. HbA1c was determined with the HPLC Biorad method (reference range 4.3 -6.1). The same laboratory was used for all HbA1c measures in this study. We used the American Diabetes Association (ADA) guidelines for HbA1c, which recommends an HbA1c of <7.0% and additional intervention when HbA1c exceeds 8.0% (3). We used these guidelines to classify patients in poor (≥ 8.0%), and satisfactory (<8.0 %) control. We obtained self-ratings of the number of hypoglycaemia (too low blood glucose) during the previous four weeks and severe hypoglycaemia for which assistance was required.

Health related Quality of life (HR-QoL) was measured with the *RAND-36* (35;36) and the DQOL (37;38). Four of the original nine subscales of the RAND-36 were used measuring the core aspects of HR-QoL, i.e. physical functioning, social functioning, mental health and vitality. Each scale was transformed to a 100-points scale with 0 representing the lowest possible and 100 representing the highest possible HR-QoL in the domain measured. The *Diabetes Quality of Life Measure (DQOL)* is applicable for both type-1 and type-2 diabetes patients (38). In this study, sub-scales for satisfaction with treatment and impact of treatment were used. Scales were transformed to 100-points scales with higher scores representing better HR-QoL.

In diabetes research, empowerment has been measured in several ways and generally included aspects of perceived control and coping with

diabetes (31;39;40). As *indicators of empowerment*, we used questionnaires for diabetes-specific health locus of control and diabetes-specific coping. MIEP largely focuses on patients' own resources to handle their diabetes and encourages an active approach to problems regarding self-management, both of which are reflected by these questionnaires with items relevant to diabetes and its treatment. Empowered patients should show more active and problem-directed coping, instead of avoidance and passive coping. Furthermore, empowered patients are considered to be more internally oriented, which is associated with better self-management outcomes (11;15;41).

Health locus of control: Wallston (42;43) defined three health loci of control (HLOC): (1) *Internal HLOC*: the extent to which patients perceive their health (diabetes control) to be dependent on their own behaviour. (2) *Powerful others HLOC*: the extent to which patients perceive their health (diabetes control) to be dependent on powerful others, i.e. the physician. (3) *Chance HLOC*: the extent to which patients perceive their health (diabetes control) to be dependent on chance factors, i.e. fate or luck. We used the Dutch version of the diabetes specific health locus of control scale for diabetes patients (44). This instrument has three sub-scales, each consisting of six items with 6-point agree-disagree Likert-scales. Scores for the sub-scales range from 6 to 36, in which higher scores mean higher orientation on the sub-scale.

Coping: The revised Diabetes Coping Measure (45) was used. The original DCM provided three sub-scales that assessed *avoidance coping, passive resignation coping and tackling spirit coping*. The revised DCM has 5 items from each sub-scale and introduces a fourth scale (6 items) derived from the ATT39 measuring *diabetes integration* (46). All subscales were scored from 0-100. High scores on diabetes integration and tackling spirit sub-scales indicate adaptive coping behaviour, whereas high scores on avoidance and passive resignation sub-scales indicate less adaptive coping in diabetes.

3.2.4 Statistics

Changes over time were tested for statistical significance with paired samples t-tests and the magnitude of changes was quantified by calculating effect sizes according to Cohen's method (47). Effect sizes were calculated by dividing the mean change (T1 - T0) by the standard deviation (SD) of that change. We used ANOVA analysis with Bonferroni post-hoc tests to compare participants before and after the intervention with the reference group.

Since patients possibly had different treatment goals and to gain better insight into the programme's effects, patients were sub-divided according to baseline HbA1c and mental health scores. Patients were divided into two classes of glycaemic control: fair to good (satisfactory) control (HbA1c<8.0) and poor control (HbA1c > 8.0). Independently of their HbA1c, patients were classified using the Rand-36 subscale for mental health. In

accordance with several studies that measured mental health using the Rand-36 in various chronic conditions including diabetes (48;49), we distinguished two groups: those with poor mental health (score < 60), and those with satisfactory mental health (score ≥ 60). Student's t-tests were used to compare the different sub-groups. To determine effects over time within subgroups, effect sizes were calculated and significance tested with paired samples t-tests. Furthermore, we calculated how many patients improved or deteriorated relevantly, and how many stayed relatively stable. A change of at least 0.5% HbA1c was considered relevant. With respect to mental health, individual changes of large effect sizes (0.8 SD) (47) were considered relevant. In the 37 patients with two pre-MIEP HbA1c measures we determined whether patients only improved after they participated in MIEP by means of General Linear Models (GLM) for Repeated Measures (ANOVA for repeated measures).

3.3 Results

3.3.1 Demographics

At baseline, mean age of the participants was 45.8 (± 14.3) years, compared to 48.1 (± 13.3) in the reference group (NS). About 47% were men in both groups. Mean diabetes duration was 12.8 (± 10.3) years in the participants and 18.2 (± 12.8) in the reference group ($t = -1.84$; $p < .001$). Forty-four percent of the participants had type-1 diabetes and 68% of the reference group, but all patients used insulin and treatment regimes were comparable in type 1 and type 2 patients.

3.3.2 Programme effects

The main aim of this study was to determine effects of MIEP. Table 1 shows that, in general, patients improved in several outcomes during MIEP, with effect sizes being small (around .20) to medium (around .50). Paired samples t-test showed that patients improved significantly in HbA1c, mental health and satisfaction with treatment and patients showed significantly less chance and powerful others locus of control and less Coping $_{\text{passive resignation}}$. Physical functioning was somewhat worse after MIEP. Given that we performed multiple comparisons, it has to be considered that some effects were only significant at $p<.05$. At T0, participants of MIEP had worse scores on several measures compared to the reference group of non-referred outpatients. At T1, differences between the participants of MIEP and the reference group became much smaller; participants only had worse physical functioning and $DQOL_{\text{impact}}$.

The two HbA1c values from the 37 patients measured in the year before MIEP did not differ from HbA1c at baseline (See table 2). Due to the small number of patients, GLM did not reveal any significant effect over time in this subgroup. However, these data do not indicate any changes before MIEP, but only improvement after T0.

Table 1: Overall effects of MIEP

	Measurement			**Reference group**
	T0 M (SD)	T1 M (SD)	Effect Size	M (SD)
Metabolic control:				
HbA1c	8.39 (1.19)**	7.87 (1.13)	0.46***	7.96 (1.24)
Hypoglycaemia (4 weeks)	5.52 (7.82)	6.24 (8.65)		5.58 (6.77)
Severe Hypoglycaemia (none in last 4 weeks)	86%	91%		86%
Health related Quality of Life:				
Rand-36 (range 0-100)				
Mental Health	68.1 (19.1)*	73.2 (19.2)	0.40***	73.0 (16.6)
Vitality	56.5 (23.4)	58.5 (20.3)	0.13	60.4 (20.0)
Social functioning	76.3 (26.4)	76.5 (23.9)	0.04	80.8 (22.9)
Physical functioning	78.4 (21.7)	74.3 (23.8)*	0.29**	80.8 (21.5)
DQOL: (range 0-100)				
Impact	70.0 (11.5)**	68.7 (11.0)***	0.05	75.0 (11.5)
Satisfaction	66.1 (13.7)*	67.8 (11.0)	0.22*	70.4 (15.5)
Indicators of Empowerment:				
Health Locus of Control (range 0-30)				
Internal	20.0 (5.2)	20.9 (5.1)	0.18	21.0 (4.6)
Chance	11.2 (5.0)*	10.1 (5.2)	0.28*	9.9 (5.4)
Powerful others	16.6 (5.9)***	14.8 (5.9)	0.40***	13.9 (6.1)
Way of Coping (0-100)				
Tackling Spirit	69.5 (14.6)	69.8 (14.9)	0.03	70.3 (14.6)
Avoidance	27.9 (25.1)	25.6 (20.8)	0.17	28.2 (22.2)
Diabetes Integration	58.7 (23.5)	57.4 (21.9)	0.03	59.9 (25.5)
Passive resignation	37.5 (21.6)***	27.6 (22.4)	0.27*	27.6 (22.4)

* p<.05; ** p<.01; ***p<.001: either of paired t-test or of comparison with reference group

Table 2: Means (SD) of pre-MIEP HbA1c compared to baseline and 3-months follow-up.

	Mean (SD) N = 37
1st Pre MIEP[a]	8.56 (1.29)
2nd Pre MIEP[b]	8.46 (1.16)
Mean pre MIEP	8.51 (1.17)
T0 (baseline)	8.51 (1.19)
T1 (3 months Follow-up)	8.08 (1.07)

[a] Approximately 12 months prior to MIEP

[b] Approximately 6 months prior to MIEP

Table 3: Pre- and Post-measurements of glycaemic control, HR-QoL, self-care, and empowerment, subdivided for patients with baseline HbA1c below and over 8.0%

	HbA1c < 8.0% (N=33)			HbA1c ≥ 8.0% (N=56)			High vs. low sub-groups	
	T0 M (SD)	T1 M (SD)	T0 ES*	T1 M (SD)	T1 M (SD)	ES*	T0 t	T1 t
Glycaemic control:								
HbA1c	7.27 (.54)	7.29 (.77)	.05	9.04 (.96)	8.21 (1.17)	.67***	-9.76***	-4.02***
Hypoglycaemia (4 weeks)	8.61 (11.03)	7.34 (11.69)	.12	3.56 (3.78)	5.60 (6.28)	.27	3.16**	.86
Health related Quality of life								
Rand-36 (range 0-100)								
Mental health	66.8 (15.5)	73.1 (17.4)	.50**	68.9 (21.2)	73.3 (20.3)	.36*	-.50	-.05
Physical Functioning	75.6 (23.2)	75.6 (23.2)	.29	78.1 (20.5)	73.5 (24.3)	.30*	.15	.41
Social Functioning	75.8 (24.4)	76.5 (25.7)	.03	76.6 (27.8)	76.6 (23.0)	.04	-.16	.01
Vitality	55.0 (19.9)	58.0 (20.5)	.16	57.4 (25.5)	58.8 (20.3)	.11	-.46	-.16
DQOL: (range 0-100)								
Impact	68.8 (11.0)	69.5 (10.9)	.18	70.7 (11.8)	68.1 (11.1)	.16	-.74	-.57
Satisfaction	66.5 (13.0)	69.3 (11.8)	.27	65.9 (14.3)	66.9 (11.2)	.19	.18	.94
Indicators of Empowerment:								
Health Locus of Control (range 0-30)								
Internal	20.1 (5.2)	20.1 (5.3)	.00	20.0 (5.2)	21.4 (5.0)	.29*	.09	-1.19
Chance	10.3 (4.6)	9.1 (5.2)	.30	11.8 (5.2)	10.7 (5.2)	.27	-1.33	-1.46
Powerful Others	15.1 (7.0)	13.0 (6.6)	.37*	17.7 (5.0)	15.9 (5.2)	.42**	-2.00*	-2.24*
Way of Coping (range 0-100)								
Tackling Spirit	70.0 (12.7)	69.9 (13.8)	.01	69.1 (15.8)	69.7 (15.8)	.06	.27	.06
Avoidance	23.6 (22.7)	19.2 (18.9)	.23	30.6 (26.3)	29.5 (21.1)	.13	-1.25	-2.29*
Diabetes Integration	56.9 (24.9)	56.6 (22.4)	.04	59.8 (24.9)	57.9 (21.8)	.03	-.54	-.26
Passive resignation	33.6 (21.0)	27.7 (21.4)	.34	39.9 (21.8)	35.2 (23.1)	.24	-1.31	-1.51

* ES = Effect size; (T1 - T0) / SD (T1-T0) * $p < .05$ ** $p < .01$ *** $p < .001$

Table 4: Pre- and Post-measurements of glycaemic control, HR-QoL, self-care, and empowerment, subdivided for patients with baseline mental health scores below and over 60

	Mental health ≤ 60 (N=30)			**Mental health > 60 (N=58)**			**High vs. low sub-groups**	
	T0	T1		T0	T1		T0	T1
	M (SD)	M (SD)	ES[a]	M (SD)	M (SD)	ES[a]	t	t
Glycaemic control:								
HbA1c	8.45 (1.16)	7.88 (1.15)	.40*	8.37 (1.25)	7.87 (1.15)	.52***	.28	.03
Hypoglycaemia (4 weeks)	7.14 (11.4)	5.64 (7.25)	.13	4.72 (5.17)	6.22 (9.35)	.17	1.35	-.29
Health related Quality of life								
Rand-36 (range 0-100)								
Mental health	45.3 (13.0)	58.8 (20.3)	.76***	79.3 (9.0)	81.6 (12.6)	.20	-14.1***	-6.46***
Physical Functioning	66.8 (24.6)	65.4 (27.5)	.16	84.0 (17.7)	78.8 (20.4)	.35*	- 3.70***	-2.51***
Social Functioning	50.0 (23.3)	62.1 (24.6)	.39*	89.3 (16.3)	84.6 (19.6)	.23	- 9.02***	-4.58***
Vitality	35.7 (15.0)	45.9 (19.2)	.52*	66.7 (19.8)	65.5 (18.1)	.06	- 7.30***	-4.61***
DQoL: (range 0-100)								
Impact	61.9 (10.9)	62.6 (10.3)	.07	74.0 (9.6)	71.3 (10.9)	.13	- 5.21***	-4.54***
Satisfaction	55.1 (12.4)	62.8 (8.7)	.67**	71.6 (10.8)	72.6 (9.3)	.01	- 6.31***	-3.53***
Indicators of Empowerment:								
Health Locus of Control (range 0-30)								
Internal	19.2 (5.2)	19.5 (4.9)	.06	20.4 (5.2)	21.5 (5.2)	.27*	- 1.05	-1.65
Chance	12.4 (5.3)	9.8 (5.4)	.56**	10.7 (4.9)	9.8 (5.4)	.18	1.45	.40
Powerful Others	17.2 (6.5)	14.1 (5.5)	.62**	16.4 (5.7)	15.0 (6.2)	.29*	-.62	- .69
Way of Coping (range 0-100)								
Tackling Spirit	67.3 (13.6)	68.3 (14.7)	.07	70.5 (15.1)	70.8 (15.6)	.01	-.95	- .71
Avoidance	34.1 (28.4)	24.3 (20.9)	.37	24.8 (22.9)	25.1 (20.2)	.02	1.62	- .17
Diabetes Integration	44.9 (25.3)	52.3 (24.5)	.55**	65.4 (19.4)	61.2 (19.6)	.31*	-4.12***	-1.79
Passive resignation	48.8 (20.0)	34.8 (24.2)	.59***	31.9 (20.2)	30.1 (21.9)	.09	3.62**	.89

[a] ES = Effect size; (T1 - T0) / SD (T1-T0) * p < .05 ** p < .01 *** p < .00

3.3.3 Sub-groups of patients

To meet the fact that patients could have different goals and to better place outcomes, patients were sub-divided according to their baseline HbA1c and mental health. Fifty-six patients (63%) had poor glycaemic control, of which 18 indicated low mental health as well. Twelve patients (13%) had acceptable HbA1c but poor mental health. Twenty-one patients (24%) with HbA1c < 8.0% had mental health scores over 60, which means that nor HbA1c nor mental health fully could cover their reason for inclusion to MIEP. Of these 21 patients, 7 reported at least one sever hypoglycemic episode or > 10 non-severe hypoglycemia. To conclude, glycaemic control and mental health scores indicated for most patients their reasons for participation in MIEP; 14 of the 99 patients could not be classified using information on glycaemic control and mental health. Given that glycaemic control and mental health did not correlate (r = .07, ns.), programme effects were calculated separately for both subgroups.

3.3.4 Programme effects for patients with satisfactory and poor glycaemic control

Few differences were found between subgroups with satisfactory and poor HbA1c in HR-QoL and indicators of empowerment. By definition, the groups differed in baseline HbA1c. Table 3 shows that the poor control group (HbA1c ≥ 8.0%) improved significantly in HbA1c, although HbA1c remained significantly higher than in the group with satisfactory glycaemic control. At T0, patients with HbA1c < 8.0% had significant more hypoglycaemia, but at T1, this difference was not significant anymore. In the HbA1c < 8.0% group, the number of patients that reported severe hypoglycaemia diminished during the study period. Most patients (64%) in the poor control group showed a clinically relevant decline in HbA1c of at least 0.5 and 38% of this group reached an HbA1c of ≤ 8.0% after treatment. In the group of patients with satisfactory glycaemic control at baseline, 73% consolidated this control (± 0.5%), 15% improved relevantly (> 0.5%) and 12% deteriorated (> 0.5%).

Mental health improved in both groups. The subgroups did not differ with respect to HR-QoL. Both groups indicated less $HLOC_{powerful\ others}$ at T0. The HbA1c ≥ 8.0% group also improved significantly at $HLOC_{internal}$. Both at T0 and T1, patients with HbA1c ≥ 8.0% indicated more $HLOC_{powerful\ others}$ and more $Coping_{avoidance}$, which was only significant at T1.

3.3.5 Programme effects for patients with poor and satisfactory mental health

In contrast to the subgroups based on HbA1c, the subgroups based on mental health differed in all other HR-QoL domains as well (see Table 4). At T1, the differences in QoL became smaller and the low mental health group improved significantly in mental health, social functioning, vitality and

$DQOL_{satisfaction}$. The mental health >60 group which had also rather good scores in other domains, did not improve in any HR-QoL measure. Remarkably, this group worsened in physical functioning. Both groups improved about equally in HbA1c.

In the poor mental health group, 54% improved relevantly at mental health (large effect of >0.8 SD(47), >15 points in this study) and 14% in the mental health >60 group. Only 7% in the low mental health group and 9% in the high mental health group deteriorated more than 0.8 SD.

At baseline the poor mental health group indicated less Coping $_{diabetes\ integration}$ and Coping $_{passive\ resignation}$ than the group with better mental health. The group with poor mental health improved significantly at most indicators of empowerment and at T1 no significant differences were found anymore. The mental health > 60 group only showed less $HLOC_{powerful\ others}$ after MIEP.

3.4 Discussion

In 89 patients, we evaluated a Multidisciplinary Intensive Education Programme (MIEP) for patients with diabetes mellitus with prolonged self-management difficulties despite intensive regular care. These patients were compared to a reference group of 231 non-referred outpatients. Overall, patients improved their glycaemic control and HR-QoL. After MIEP, participants differed little from the reference group, which could be considered average diabetic patients treated in a outpatient clinic. In particular, patients with poor baseline values (HbA1c > 8.0%) improved their glycaemic control. More than half of all patients achieved a substantial, clinically relevant reduction in their HbA1c, and 38% of the poor controlled patients could be classified as having fair to good HbA1c after treatment. Furthermore, the number of patients that reported severe hypoglycaemia was reduced to almost none, although overall hypoglycaemic episodes did not diminish. This is probably caused by a tighter blood glucose control, which is often related to more hypoglycaemia (4). Patients with poor mental health indicated lower health related quality of life on most other sub-scales as well. At follow-up, differences between sub-groups with poor and satisfactory mental health had become smaller. Remarkably, patients with poor mental health scored lower on all other HR-QoL scales as well. Patients with poor mental health were less empowered at baseline, but improved significantly. At follow-up, no differences in empowerment were found between these subgroups.

Diabetes affects virtually all aspects of life. Diabetes treatment is complex and makes a heavy demand on patients' own responsibility. For these reasons, an interdisciplinary, integral approach, which has multiple excuses to intervene, is preferable in the specific target group of MIEP. The

rather intensive outpatient care participants already received has been found inadequate for these patients with prolonged and complex diabetes-related problems. The integrated approach, however, makes it hard to detect what aspects of MIEP exactly contributed to the outcomes.

Alternative explanations for programme effects might be regression to the mean, or purely the additional attention resulting from participating in MIEP. The study design applied with a single pre and one post measure is prone to effects of regression to the mean, i.e. that persons with low scores will improve on the second measurement by chance (50). However, it has to be noted that patients included in MIEP had already received prolonged intensive regular care and education without achieving their treatment goals. Data on HbA1c measured in the period before MIEP support this. Two pre-measures and baseline HbA1c did not differ and only after MIEP a significant improvement in HbA1c was found. Moreover, few patients in the low HbA1c group and in the satisfactory mental health group deteriorated, which suggests at the most a minor effect of regression to the mean.

As shown in two large prospective diabetes studies (DCCT and UKPDS), the reduction of HbA1c in the poor control group, when consolidated, will greatly reduce the risk of long-term complications (1;2). Even though most patients in this group still have elevated HbA1c. Furthermore, attaining good HR-QoL is one of the core goals of diabetes treatment. The apparent improvements in mental health clearly showed effects of MIEP in this respect. We recognise that consolidation of effects is important to really endorse MIEP's success, for which long-term follow-up data will be collected. Other education programmes for patients with self-management difficulties found varying long-term effects. The holistic education programme of Bott et al. (27) did not show improvement in HbA1c 17.5 months after treatment, whereas 9 months after cognitive analytic therapy, poorly controlled patients showed a reduction of 2.0% HbA1c (24). We used the empowerment approach in MIEP to try to alter behavioural patterns permanently.

Glasgow and Osteen (20) mentioned the importance of measuring process variables, such as coping, in diabetes education. They substantiated that programme characteristics have a major influence on process variables, which in turn affect outcome measurements. As indicators of empowerment, we considered health locus of control and coping important process variables. Few differences were found in levels of empowerment between the subgroups of HbA1c and no association was found between empowerment and change in HbA1c. Although HbA1c improved, our results do not reveal whether this improvement stemmed from changes in empowerment. Analyses of the mental health sub-groups showed that patients with poor mental health were less empowered at baseline. MIEP seems an effective way to improve empowerment in these patients.

To some extent the classification of patients into the sub-groups was arbitrary; the categories of glycaemic control were based on ADA guidelines (3) and categories of mental health were based on several studies on chronic illness using the Rand-36 quality of life questionnaire (48;49). In reality, cut-off points between good and poor control and between poor and satisfactory mental health are not that strictly defined, but tend to flow into each other. For the purpose of this study we used a dichotomy, as it enabled us to gain insight into the role of inclusion criteria in programme effects. However, this method is a rough presentation of patients' goals. Nevertheless, improving glycaemic control and improving psychosocial functioning were frequently mentioned goals and are also general goals of diabetes self-management (3;5).

Our results support the inclusion of patients with poor glycaemic control and/or poor mental health to optimise the effectiveness of MIEP. Nevertheless, more research is needed to develop more accurate guidelines for inclusion. This study indicates that MIEP can be a useful supplementary treatment for diabetes patients who did not reach their self-management goals in regular care.

3.5 References

(1) Diabetes Control and Complications Trial Research Group. The Effects of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329(14):977-986.

(2) UKPDS. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group [see comments]. Lancet 1998; 352(9131):837-853.

(3) American Diabetes Association (ADA). Standards of Medical Care for Patients With Diabetes Mellitus. Diabetes Care 24[Supplement 1]. 2001.

(4) Diabetes Control and Complications Trial Research Group (DCCT). Influence of intensive diabetes treatment on quality-of-life outcomes in the diabetes control and complications trial [see comments]. Diabetes Care 1996; 19(3):195-203.

(5) European Diabetes Policy Group 1998-1999. A Desktop Guide to Type 2 Diabetes Mellitus. International Diabetes Federation European Region . 1999.

(6) Hanestad BR, Albrektsen G. Quality of life, perceived difficulties in adherence to a diabetes regimen, and blood glucose control. Diabet Med 1991; 8(8):759-764.

(7) Dalewitz J, Khan N, Hershey CO. Barriers to control of blood glucose in diabetes mellitus. Am J Med Qual 2000; 15(1):16-25.

(8) Lloyd CE, Dyer PH, Lancashire RJ, Harris T, Daniels JE, Barnett AH. Association between stress and glycemic control in adults with type 1 (insulin-dependent) diabetes. Diabetes Care 1999; 22(8):1278-1283.
(9) Schwartz LS, Coulson LR, Toovy D, Lyons JS, Flaherty JA. A biopsychosocial treatment approach to the management of diabetes mellitus. Gen Hosp Psychiatry 1991; 13(1):19-26.
(10) Jacobson AM. The psychological care of patients with insulin-dependent diabetes mellitus. N Engl J Med 1996; 334(19):1249-1253.
(11) Tillotson LM, Smith MS. Locus of control, social support, and adherence to the diabetes regimen. Diabetes Educ 1996; 22(2):133-139.
(12) Talbot F, Nouwen A, Gingras J, Belanger A, Audet J. Relations of diabetes intrusiveness and personal control to symptoms of depression among adults with diabetes. Health Psychology 1999; 18(5):537-542.
(13) Rubin RR, Peyrot M. Psychosocial problems and interventions in diabetes. A review of the literature. Diabetes Care 1992; 15(11):1640-1657.
(14) Macrodimitris SD, Endler NS. Coping, control, and adjustment in Type 2 diabetes. Health Psychol 2001; 20(3):208-216.
(15) Watkins KW, Connell CM, Fitzgerald JT, Klem L, Hickey T, Ingersoll-Dayton B. Effect of adults' self-regulation of diabetes on quality-of-life outcomes. Diabetes Care 2000; 23(10):1511-1515.
(16) Mulcahy K, Peeples M, Tomky D, Weaver T. National Diabetes Education Outcomes System: Application to Practice. Diabetes Educ 2000; 26(6):957-964.
(17) Berger M, Muhlhauser I. Diabetes care and patient-oriented outcomes. JAMA 1999; 281(18):1676-1678.
(18) Peyrot M. Behavior change in diabetes education. Diabetes Educ 1999; 25(6 Suppl):62-73.
(19) Norris SL, Engelgau MM, Narayan KM. Effectiveness of Self-Management Training in Type 2 Diabetes; A Systematic Review of Randomized Controlled Trials. Diabetes Care 2001; 24(3):561-587.
(20) Glasgow RE, Osteen VL. Evaluating diabetes education. Are we measuring the most important outcomes? Diabetes Care 1992; 15(10):1423-1432.
(21) Peyrot M, Rubin RR. Modeling the effect of diabetes education on glycemic control. Diabetes Educ 1994; 20(2):143-148.
(22) Funnell MM, Anderson RM, Arnold MS, Barr PA, Donnelly M, Johnson PD et al. Empowerment: an idea whose time has come in diabetes education. Diabetes Educ 1991; 17(1):37-41.
(23) Glasgow RE, Eakin EG, Toobert DJ. How generalizable are the results of diabetes self-management research? The impact of participation and attrition. Diabetes Educ 1996; 22(6):573-2,584.
(24) Fosbury JA, Bosley CM, Ryle A, Sonksen PH, Judd SL. A trial of cognitive analytic therapy in poorly controlled type I patients. Diabetes Care 1997; 20(6):959-964.

(25) Snoek FJ, Van der Ven NCW, Lubach C. Cognitive Behavioral Group Training for Poorly Controlled Type 1 Diabetes Patients: A Psychoeducational Approach. Diabetes Spectrum 1999; 12(3):147-152.
(26) Ven NCWvd, Chatrou M, Snoek FJ. Cognitive-Behavioural Group Training. In: Snoek FJ, Skinner TC, editors. Psychology in Diabetes Care. Chichester: John Wiley & Sons, LTD, 2000: 207-234.
(27) Bott U, Bott S, Hemmann D, Berger M. Evaluation of a holistic treatment and teaching programme for patients with Type 1 diabetes who failed to achieve their therapeutic goals under intensified insulin therapy. Diabet Med 2000; 17(9):635-643.
(28) Keers JC, Blaauwwiekel EE, Hania M, Bouma J, Scholten-Jaegers SMHJ, Sanderman R et al. Diabetes rehabilitation: development and first results of a Multidisciplinary Intensive Education Program for patients with prolonged self-management difficulties. Patient Education and Counseling 2004; 52(2): 151-157.
(29) Glasgow RE. Outcomes of and for diabetes education research. Diabetes Educ 1999; 25(6 Suppl):74-88.
(30) Anderson RM, Funnell MM, Carlson A, Saleh-Statin N, Cradock S, Skinner TC. Facilitating Self-care Through Empowerment. In: Snoek FJ, Skinner TC, editors. Psychology in Diabetes Care. Chichester: John Wiley & Sons, LTD, 2000: 69-98.
(31) Anderson RM, Funnell MM, Barr PA, Dedrick RF, Davis WK. Learning to empower patients. Results of professional education program for diabetes educators [published erratum appears in Diabetes Care 1991 Oct;14(10):933]. Diabetes Care 1991; 14(7):584-590.
(32) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1997; 18:943-949.
(33) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1997; 18:943-949.
(34) Colagiuri R, Colagiuri S, Naidu V. Can patients set their own educational priorities? Diabetes Res Clin Pract 1995; 30(2):131-136.
(35) Ware JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36) : I. Conceptual framework and item selection. Med Care 1992; 30(6):473-483.
(36) Van der Zee K, Sanderman R, Heyink JW, De Haes H. Psychometric qualities of the RAND 36-item Health Survey 1.0: a multidimensional measure of general health status. Int J Behav Med 1996; 3(2):104-122.
(37) Diabetes Control and Complications Trial Research Group. Reliability and validity of a diabetes quality-of-life measure for the diabetes control and complications trial (DCCT). The DCCT Research Group. Diabetes Care 1988; 11(9):725-732.

(38) Jacobson AM, Diabetes Control and Complications Trial Research Group. The Diabetes Quality of Life Measure. In: Bradley C, editor. Handbook of Psychology and Diabetes. Amsterdam: Harwood Academic Publishers, 1994: 65-87.
(39) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1997; 18:943-949.
(40) Feste C. A practical look at patient empowerment. Diabetes Care 1992; 15(7):922-925.
(41) Surgenor LJ, Horn J, Hudson SM, Lunt H, Tennent J. Metabolic control and psychological sense of control in women with diabetes mellitus. Alternative considerations of the relationship. J Psychosom Res 2000; 49(4):267-273.
(42) Wallston K, Stein M, Smith C. Form C of the MHLC scales: A condition-specific measure of locus of control. Journal of Personality Assessment 1994; Vol 63(3):534-553.
(43) Wallston KA, Wallston BS, DeVellis R. Development of the Multidimensional Health Locus of Control (MHLC) Scales. Health Educ Monogr 1978; 6(2):160-170.
(44) Halfens R. Locus of Control:De beheersingsorientatie in relatie tot ziekte- en gezondheidsgedrag. Limburg University, 1985.
(45) Welch G. Diabetes Coping Measure. In: Bradley C, editor. Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice. London: Harwood Academic Publishers, 1994: 400.
(46) Dunn SM, Bryson JM, Hoskins PL, Alford JB, Handelsman DJ, Turtle JR. Development of the diabetes knowledge (DKN) scales: forms DKNA, DKNB, and DKNC. Diabetes Care 1984; 7(1):36-41.
(47) Cohen J. A power primer. Psychol Bull 1992; 112(1):155-159.
(48) Kempen GIJM, Ormel J, Brilman EI, Relyveld J. Adaptive responses among Dutch elderly: the impact of eight chronic medical conditions on health-related quality of life. Am J Public Health 1997; 87(1):38-44.
(49) Kempen GIJM, Miedema I, Van den Bos GAM, Ormel J. Relationship of domain-specific measures of health to perceived overall health among older subjects. J Clin Epidemiol 1998; 51(1):11-18.
(50) Campbell DT, Kenny DA. A primer on Regression Artifacts. 1 ed. New York: The Guilford Press, 1999.

4

One-year follow-up effects of diabetes rehabilitation for patients with prolonged self-management difficulties

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Abstract

Aim

The aim of this study is to determine effects and the role of indicators of empowerment of a Multidisciplinary Intensive Education Programme (MIEP) for diabetic patients with prolonged self-management difficulties.

Methods

Glycaemic control (HbA1c), health-related quality of life (HR-QoL) and indicators of empowerment (health locus of control and coping) were measured in 99 participants of MIEP at baseline (T0), 3 (T1) and 12 months (T2) follow-up and in 231 non-referred consecutive outpatients.

Results

HbA1c improved at T2, although initial improvement was partially lost. Patients improved in most HR-QoL domains, without any relapse at T2. At T2, participants no longer differed from the average outpatients in any outcome. Initially, men's and women's HbA1c improved equally, but at T2 women consolidated improvement, whereas men relapsed. After MIEP, patients became more empowered (both at T1 and T2), explaining additional variance in HR-QoL improvement.

Conclusion

The aim of MIEP to empower patients, rather than trying to solve problems for them, seems effective.

4.1 Introduction

A considerable number of diabetic patients does not gain sufficient benefit from regular care and experiences difficulties in maintaining adequate self-management, as manifested in poor glycaemic control (1;2), measured by glycated haemoglobin (HbA1c) and psychosocial problems (1-5). Additional intensive education, self-management and psychological interventions can support these patients in optimising glycaemic control and health-related quality of life (HR-QoL), both equally important outcomes of diabetes care (6;7).

Several characteristics of intensive diabetes self-management interventions contribute to their effectiveness. These relatively time-consuming and expensive interventions should be reserved for patients at particular high risk and for whom intensive standard care is insufficient (8). Traditional diabetes education tends to focus primarily on improvement of knowledge in order to improve self-management, but knowledge alone does not result in improved glycaemic control, nor does it produce behaviour change (9-12). Interventions are often effective in the short run but consolidation of effects is much more limited (9). To achieve long term self-management effects, changes in patients' attitudes and motivation are more important than purely improving knowledge (13). Effective education programmes must be individualised to a person's lifestyle, must respect individual habits, incorporate social support and must be reinforced over time (14). Treatment that incorporates metabolic and psychosocial factors is most effective, requiring close collaboration between diabetologists, diabetes nurse specialists, psychologists and other team members (15). Not only the immediate effects of the intervention should be considered but also consolidation of these effects (9).

We developed a diabetes rehabilitation programme (Multidisciplinary Intensive Education Programme (MIEP) (16) for patients with prolonged self-management difficulties; e.g. poor glycaemic control and/or frequent or severe hypoglycaemia and/or diabetes-related psychosocial problems that could be unsatisfactorily treated in regular diabetes care. MIEP aims to empower patients to manage their diabetes in order to achieve more lasting effects in glycaemic control and HR-QoL. The translation from the education setting to real life situations is a key element in supporting patients integrating diabetes self-management into their lives. Since prolonged self-management difficulties are often clustered and usually do not only involve knowledge and skills deficits, MIEP focuses also on other education targets (17), including goal setting, problem solving and psychosocial counselling. By combining potentially effective elements of education and a strong collaboration between team members, MIEP attempts to help patients with a history of complex self-management problems that could not be treated adequately in regular care despite intensive concern.

The first aim of this study is to determine effects of MIEP in glycaemic control, HR-QoL and in indicators of empowerment (i.e. coping and attribution of control over diabetes), immediately after the intervention and at one-year follow-up. The second aim is to determine whether intended increases in empowerment are related to positive HbA1c and HR-QoL outcomes, directly after MIEP and at one-year follow-up.

4.2 Patients and methods

4.2.1 Rehabilitation programme

The Multidisciplinary Intensive Education Programme (MIEP) is conducted in the Centre for Rehabilitation of the Groningen University Hospital, the Netherlands. Patients with prolonged self-management difficulties or diabetes-related psychosocial problems are referred from outpatient clinics in the region. MIEP is based on the empowerment approach (18;19) and aims to empower patients to set and attain their own treatment goals. Some elements of traditional diabetes education are integrated in MIEP as well, because empowerment and traditional transfer of knowledge are complementary (20).

MIEP comprises of ten whole days of group sessions (fixed groups of 6 to 9 patients) and some individual support over ten weeks. Follow-up visits take place at six and twelve weeks (T1) and one year (T2). The diabetes education team consists of a diabetes nurse specialist, diabetologist, dietician, social worker, psychologist, physiotherapist, occupational therapist and an activity therapist, who work together intensively. MIEP highlights a range of diabetes-related topics and has modules on self-management, diet, exercise, daily activities and employment, the psychosocial aspects of diabetes and behavioural coping strategies. The programme uses a four-phase learning sequence. First a topic is introduced, followed by group discussion or practice. In the third phase, patients plan how to fit in a particular aspect into their daily lives, which is subsequently evaluated in the fourth phase. The contents are thus made relevant to the patients' own experiences and goals. Education directed solely at patients' own priorities does carry a risk of missing essential aspects of diabetes self-management (21). However, by providing an educational framework, the coverage of all essential aspects is ensured.

4.2.2 Participants

In 1999 and 2000, 161 patients enrolled in MIEP, of whom 154 (96%) participated in the study and completed the baseline assessment (T0). Patients <18 or >75 years old, patients with severe co-morbidity (physically and mentally) or poor command of the Dutch language were excluded. The first

measurement was obtained when the patients had their admission interviews. Follow-up questionnaires were mailed to the patients' home addresses to be obtained at the 3-months (T1) and 1-year (T2) follow-up visits. Additionally, we obtained 2 HbA1c measurements in the year previous to MIEP from patients whose values had regularly been determined in the same laboratory. This was the case for 47 participants.

To obtain reference values, we selected 330 consecutive non-referred outpatients from the diabetes clinic of Groningen University Hospital, using the same exclusion criteria as MIEP. Two-hundred-and-thirty-one patients (70.0%) took part in the study after informed consent, completed one questionnaire and gave permission for using their most recent HbA1c measurement and that of approximately -4 and -8 months.

4.2.3 Measures

Glycaemic control was measured by means of HbA1c, a standard measure in diabetes for the percentage of glycated haemoglobin, indicating glycaemic control in the previous 6 to 8 weeks. An HbA1c of ≥ 8.0% was considered poor glycaemic control (6). The number of hypoglycaemia encountered over the previous four weeks and the number of severe hypoglycaemia for which assistance was required were obtained by self-ratings.

Health-related quality of life (HR-QoL) was measured using the Rand-36 questionnaire (22;23). Four of the original 9 subscales were applied to measure the core aspects of HR-QoL; physical functioning, social functioning, mental health and vitality. The subscales were transformed to 100-points scales with 0 representing the lowest and 100 the highest possible HR-QoL.

In diabetes research, several instruments have been used to indicate patients' feelings of empowerment. In general, they include aspects of perceived control and coping with diabetes (18;24;25;26). As indicators of empowerment, we used diabetes-specific questionnaires for health locus of control and coping. These questionnaires reflect MIEP's focus on the patients' own resources in handling their diabetes and the encouragement of an active approach to problems regarding self-management. Empowered patients should indicate more active and problem-directed coping, instead of avoidance and passive coping. Furthermore, empowered patients are considered to be more internally oriented, associated with better self-management outcomes (5;27;28).

Wallston (29;30) defined three health loci of control (HLOC): internal, chance and powerful others. $HLOC_{internal}$ reflects the extent to which patients perceive their health (diabetes control) to be dependent on their own behaviour. $HLOC_{chance}$ is the extent to which patients perceive their diabetes control to be dependent on chance factors (i.e. fate or luck). $HLOC_{powerful\ others}$ indicates whether patients perceive their diabetes control to be dependent on

influential others, i.e. the physician. We used the Dutch diabetes-specific version of this scale (31). This instrument has three subscales, each consisting of six items with 6-point agree-disagree Likert-scales. Scores were transformed to scores ranging from 0 to 100, where higher scores meant higher orientation on the subscale.

The revised Diabetes Coping Measure (DCM) (32) was used. The revised DCM has 3 5-item subscales for tackling spirit coping, avoidance coping, and passive resignation, and a fourth subscale (6 items), derived from the ATT39, measuring diabetes integration (33). All subscales were scored from 0-100. High scores on $Coping_{integration}$ and $Coping_{tackling\ spirit}$ indicate adaptive coping behaviour, whereas high scores on $Coping_{avoidance}$ and $Coping_{passive\ resignation}$ indicate poorer coping.

4.2.4 Statistical analysis

SPSS 10.0 for Windows (SPSS, Chicago) was used for statistical analysis. To analyse patterns of change over time in glycaemic control, HR-QoL and determinants of empowerment general linear models (GLM) for repeated measures (ANOVA for repeated measures) were applied. Within-subject factors for HbA1c, the 4 subscales for HR-QoL and the 7 indicators of empowerment (3 x HLOC, 4 x Coping) were defined in three separate analyses. Both linear and quadratic trends were calculated (34). Linear trends test whether a straight line best fits the 3 assessments, meaning that patients improved throughout the entire study period. Quadratic trends test whether part of a parabola fits the assessments and determine if patients especially improved during the programme, and if effects levelled off in the follow-up period. For the 47 patients with two pre-MIEP HbA1c measures, a cubic (s-bended) trend was also determined, to test whether HbA1c improved only after participation in MIEP.

We compared the means of MIEP participants to the reference group of 231 outpatients at each measurement using independent samples t-tests. For the 178 outpatients with two HbA1c pre-measures and the poorly regulated (HbA1c $\geq$ 8.0%) outpatients, changes over time were determined using GLM.

Linear regression analyses were applied to determine whether intended improvements in empowerment were related to improvements in glycaemic control and HR-QoL. After controlling for the baseline value of the outcome, age and gender, we tested whether short-term changes (T1-T0) in indicators of empowerment were predictive for short-term outcomes. Stepwise regression was used where predictors with highest significant additional predictive variance were subsequently entered in the model. Controlled-for variables were entered in a first step, using the enter method. For consolidation of effects we calculated changes in outcomes after MIEP (T2-T1). After controlling for baseline measure, age and gender, the indicators of empowerment (T2-T1) were then tested for.

4.3 Results

4.3.1 Patients

Four patients discontinued MIEP for motivational reasons and of the 150 participants who completed the programme, 118 (79%) filled in a second questionnaire (T1). One hundred and twenty-seven participants visited the one-year follow-up session and had their HbA1c measured of whom 99 (78%) completed the third questionnaire (T2). Patients who stopped MIEP between T0 and T1 (N=4) or between T1 and T2 (N=23) had significantly higher T0 HbA1c (8.94 vs. 8.36, p=.03) and a lower T0 $Coping_{integration}$ (48 vs. 60, p=.04).

Compared to the reference group, patients participating in MIEP had been more recently diagnosed with diabetes (12.8 ± 10.3, vs. 18.2 ± 12.8 years) and more often had type 2 diabetes (55% vs. 32 %). The mean age of the MIEP participants was 48 (±14) years and 53% were female, which did not significantly differ from the reference group (mean: 48 ± 13 years, 54% female). Six percent of the participants did not use insulin, remaining constant after MIEP, and 20% of the reference group did not use insulin (p = .005). At T0, participants had higher HbA1c, worse HR-QoL on all four subscales and indicated being less empowered on some subscales than the reference group (see Table 1). These differences between average outpatients and MIEP participants illustrate the broad area of self-management difficulties of the specific target group of MIEP.

4.3.2 Effects of MIEP

Glycaemic control

HbA1c improved over time (linear effect: $p < .001$, Table 1). However, after T1, the effect levelled off significantly (quadratic effect: $p < .001$), but at T2, mean HbA1c remained significantly improved compared to baseline. Initially, participants' HbA1c was significantly elevated compared to the reference group, but at T1 and T2 not longer differed. The mean HbA1c did not change in patients with an initial HbA1c of < 8.0%. The overall improvement was due to improvements in the initially poorly regulated patients. No significant changes in hypoglycaemia were found.

HbA1c before the intervention

Repeated measures analysis of the 47 patients with 2 additional measures in the year previous to MIEP indicated that HbA1c improved only from the time patients participated in MIEP. A cubic within-subjects contrast, although non-significant (p=.06), best fitted the four measurements indicating that HbA1c was stable until T0 (8.46 before MIEP; 8.38 at T0), then falling (8.06 at T1), and then deteriorating somewhat after MIEP (8.26 at T2). These 47 patients did not differ significantly in demographics, baseline HbA1c and HR-QoL from

the other participants. Repeated measures analysis of the 178 patients of the reference group with 2 previous HbA1c measures indicated, as expected, no changes in the 8 months period (means ranged from 7.92 till 7.96). In the 76 outpatients with HbA1c ≥ 8.0% at 8 months before data collection, mean HbA1c did not improve significantly (p =.25; means ranged from 8.91 till 8.75).

Health-related quality of life

Table 1 shows that participants of MIEP significantly improved in mental health and social functioning. The quadratic contrasts indicate no drawbacks in HR-QoL in the 3-12 months post-MIEP, and especially in the case of social functioning, patients after MIEP clearly improved further. Differences between participants and references largely disappeared after MIEP.

Indicators of empowerment

Patients became more empowered after MIEP (see Table 1). The linear within-subjects contrasts were significant for $Coping_{avoidance}$, $Coping_{passive\ resignation}$ and $HLOC_{chance}$ and $HLOC_{powerful\ others}$. Remarkably, patients further improved in $Coping_{avoidance}$, $HLOC_{chance}$ and $HLOC_{powerful\ others}$ between T1 and T2. Only in $Coping_{passive\ resignation}$ the quadratic contrast was significant, indicating that, in general, effects did not level off after 3-months follow-up. At baseline, participants of MIEP were less empowered in comparison with the reference group, but these differences largely disappeared after MIEP. Although $Coping_{passive\ resignation}$ declined in participants, it was still significantly higher than in the references at T2. On the other hand, participants had lower levels of $Coping_{avoidance}$ at one-year.

Table 1: Effects of MIEP: results of MANOVA for repeated measures as compared with the reference group. (Mean ± SD)

	Measurement			Within-subjects contrasts (p-values)		Reference group
(N =121/ 99)#	T0	T1	T2	Linear trend	Quadratic trend	(N=231)
HbA1c	8.36 ± 1.11***	7.93 ± 1.13	8.04 ± 1.05	<.001	<.001	7.96 ± 1.24
Hypoglycaemia (N in past 4 weeks)	5.1 ± 5.9	4.7 ± 4.9	4.8 ± 4.9	.664	.693	5.6 ± 6.8
Severe hypoglycaemia (% >0 times help required in past 4 weeks)	14%	9%	15%	-	-	14%
HR-QoL						
Physical functioning	74 ± 23**	72 ± 24**	74 ± 24*	.794	.238	81 ± 22
Mental health	68 ± 19**	73 ± 19	73 ± 15	.031	.081	73 ± 16
Social functioning	73 ± 27**	75 ± 23*	82 ± 21	.003	.262	81 ± 22
Vitality	54 ± 24**	57 ± 21	59 ± 19	.082	.797	60 ± 20
Determinants of empowerment						
Coping avoidance	27 ± 25	24 ± 21	21 ± 19*	.017	.793	28 ± 22
Coping passive resignation	41 ± 22***	32 ± 22	33 ± 22*	.015	.024	28 ± 22
Coping tackling spirit	70 ± 15	71 ± 14	72 ± 14	.235	.876	70 ± 15
Coping integration	57 ± 24	56 ± 22	57 ± 23	.803	.644	59 ± 24
HLOC internal	64 ± 18*	67 ± 18	65 ± 17	.622	.249	70 ± 24
HLOC chance	38 ± 18*	34 ± 15	32 ± 16	.001	.335	33 ± 18
HLOC powerful others	54 ± 19**	47 ± 19	42 ± 19	<.001	.312	46 ± 20

*/**/*** significance of independent samples t-tests with reference group

* P <.05, ** p<.01, ***p<.001

N=121 for HbA1c; N=99 for HR-QoL and determinants of empowerment

4.3.3 Determinants of effects

The T1 outcomes were predominately predicted by their baseline values. Short-term changes in empowerment were little predictive for T1 outcomes. Patients with a greater reduction in $HLOC_{chance}$ indicated higher vitality and

social functioning at T1 (Beta = -.26, p<.01 in both cases) after controlling for baseline values. This indicates that a decrease in $HLOC_{chance}$ is related to an increase in vitality and social functioning.

4.3.4 Determinants of maintenance of effects

Regression analyses revealed some interesting determinants for maintenance of effects. As shown in Table 2, gender and $Coping_{avoidance}$ predicted consolidation of HbA1c; female participants and patients who consolidated low levels of $Coping_{avoidance}$ were less likely to deteriorate 3 to 12 months post-MIEP. The mean HbA1c for women was 8.28 at T0, 7.96 at T1 and 7.90 at T2. GLM in women showed that a linear within-subjects contrast best fitted these data (p=.001). For men, mean HbA1c was 8.46 at T1, 7.92 at T1 and 8.21 at T2. These data were best represented by a quadratic contrast (p<.001).

Patients who were better able to consolidate T1 levels of $Coping_{integration}$ were more likely to maintain improvement or to further improve mental health and vitality after MIEP. Patients who were able to maintain low levels of $Coping_{passive\ resignation}$ had better outcomes at one-year follow-up. Patients who consolidated these coping styles more likely consolidated or improved physical functioning 3 to 12 months post-MIEP. To summarise, post-MIEP, maintenance of empowerment -best reflected by $Coping_{integration}$ and $Coping_{passive\ resignation}$- was associated with maintenance of effects in HR-QoL.

Table 3: Determinants of maintenance of effects after intervention (T2-T1)

Δ (T2 -T1)	Predictors (T2-T1)	ΔR^2	Beta
HbA1c	HbA1c T0		ns
	Age		ns
	Gender	.15	-.27*
	$Coping_{avoidance}$	.06	.26*
Mental health	Mental health T0	.17	-.41***
	Coping integration	.07	.27*
Vitality	Vitality T0	.07	ns
	$Coping_{integration}$	.09	.31**
Social functioning	Social functioning T0	.02	ns
	$Coping_{passive\ resignation}$	.08	-.29*
Physical functioning	Physical functioning T0	.01	ns
	$Coping_{passive\ resignation}$	.12	-.29*
	$Coping_{powerful\ others}$	.06	-.27*

* P <.05, ** p<.01, ***p<.001

4.4 Discussion

The results of this study show that the diabetes rehabilitation programme for diabetic patients with prolonged self-management difficulties has beneficial one-year effects on glycaemic control, health-related quality of life and empowerment. Patients who maintained improved levels of empowerment consolidated effects in HR-QoL better. Women were better able to retain improved HbA1c after the intervention.

Diabetes affects many aspects of life that are often strongly interrelated (3;35;36). MIEP is a multi-focus intervention where these interrelations were taken into account and aimed to help patients to better integrate diabetes into their lives. At baseline, marked differences between MIEP participants and references were found, illustrative for the specific target group of MIEP, whereas one year post-MIEP, participants barely differed from the group of average non-referred outpatients.

Some systematic reviews showed that initial improvements are vulnerable for relapse after the intervention ends (13;37;38), especially in medical outcomes (38). By focusing on patient-empowerment and the translation of education to the patients' home settings, MIEP attempted to prevent relapse. Particularly, with respect to HR-QoL and determinants of empowerment, MIEP succeeded in this and a small relapse in HbA1c was found.

In the present study, the increase in empowerment was particularly due to the reduction of maladaptive coping styles and loci of control. Apparently, MIEP particularly supports patients reducing inadequate patterns. The questionnaires used did possibly not measure all aspects of the broad paradigm of empowerment. Being a broad and relatively new paradigm (39), no consensus exists on how to measure empowerment in diabetes exactly. Several psychosocial outcomes could be considered in diabetes empowerment studies, of which the measures in our study are two options. Anderson et al. (40) recently developed a diabetes empowerment scale that is actually a measure of psychosocial self-efficacy. The use of this instrument would not have revealed the reduction in inadequate patterns of dealing with diabetes found in the present study and it was not yet available when our study was conducted.

For this study has a non-randomised design the results could be due to causes other than the intervention, e.g. regression to the mean. However, spontaneous improvement is not very likely in the MIEP-participants, because inclusion took into account that participants had a history of unsuccessful intensive regular care. These assumptions were supported by pre-MIEP HbA1c data.

Our second aim was to determine whether increases in empowerment were related to positive HbA1c and HR-QoL outcomes. Our results suggest that during the intervention period (short-term) patients

improved fairly independently of changes in empowerment. However, in order to maintain or further improve HR-QoL, it seems important to consolidate improvements in coping and health locus of control. Empowerment was only found to be little predictive for effects in HbA1c, but interestingly, women were better able to sustain improved HbA1c after MIEP. In general, men tend to engage more in unhealthy habits, e.g. Laasonen et al. (41) but to our knowledge gender-related differences in HbA1c outcomes in diabetes interventions have not been published. A clear explanation for this could not be found in our data. Observing the mean HbA1c over time, mean HbA1c decreased 0.38% from baseline to 1-year follow-up in women and 0.25% in men, which is not a large difference. The gender effect was especially due to the different routes in which effects were achieved and not that evident in the overall effect. Moreover, men had significant higher HbA1c at both baseline and 1-year follow-up. The finding that men were able to particularly improve HbA1c in the intensive intervention period (T0 till T1) but relapsed in the follow-up period, suggests that men in particular might benefit from additional ongoing contacts after the intervention focused on maintaining improved glycaemic control.

In conclusion, our results indicate that MIEP is a useful intervention for patients with prolonged self-management difficulties that could not adequately be treated in regular diabetes care. Using an empowerment approach and a focus on patients' goals, patients improve their HR-QoL and indicate that they are more empowered at one-year follow-up. Women in particular have good HbA1c outcomes at one-year follow-up. Our results suggest that post-intervention empowerment is important in patients being able to maintain or even further improve HR-QoL and HbA1c outcomes.

4.4.1 Practice Implications

Not all diabetic patients can be treated effectively in regular outpatient diabetes care. Diabetes rehabilitation offered by means of a Multidisciplinary Intensive Education Programme was effective in patients with prolonged self-management difficulties. Additional care, such as MIEP, should be considered for patients with poor glycaemic control or low health-related quality of life as it can help them to improve in these important treatment outcomes (7). Moreover, the improvements in HbA1c reduce the risks for diabetic complications (42-44). Determinants of empowerment should be considered in diabetes education, because improvements in knowledge alone do not result in long-term self-management changes. The aim of MIEP to empower patients to target their own diabetes goals, rather then trying to solve problems for them, seems effective.

4.5 References

(1) Dalewitz J, Khan N, Hershey CO. Barriers to control of blood glucose in diabetes mellitus. Am J Med Qual 2000; 15(1):16-25.
(2) Lloyd CE, Dyer PH, Lancashire RJ, Harris T, Daniels JE, Barnett AH. Association between stress and glycemic control in adults with type 1 (insulin-dependent) diabetes. Diabetes Care 1999; 22(8):1278-1283.
(3) Jacobson AM. The psychological care of patients with insulin-dependent diabetes mellitus. N Engl J Med 1996; 334(19):1249-1253.
(4) Rubin RR, Peyrot M. Psychosocial problems and interventions in diabetes. A review of the literature. Diabetes Care 1992; 15(11):1640-1657.
(5) Watkins KW, Connell CM, Fitzgerald JT, Klem L, Hickey T, Ingersoll-Dayton B. Effect of adults' self-regulation of diabetes on quality-of-life outcomes. Diabetes Care 2000; 23(10):1511-1515.
(6) American Diabetes Association (ADA). Standards of Medical Care for Patients With Diabetes Mellitus. Diabetes Care 24[Supplement 1]. 2001.
(7) Bradley C, Gamsu DS. Guidelines for encouraging psychological well-being: report of a Working Group of the World Health Organization Regional Office for Europe and International Diabetes Federation European Region St Vincent Declaration Action Programme for Diabetes. Diabet Med 1994; 11(5):510-516.
(8) Glasgow RE. A practical model of diabetes management and education. Diabetes Care 1995; 18(1):117-126.
(9) Brown SA. Interventions to promote diabetes self-management: state of the science. Diabetes Educ 1999; 25(6 Suppl):52-61.
(10) Clement S. Diabetes self-management education. Diabetes Care 1995; 18(8):1204-1214.
(11) Coates VE, Boore JR. Knowledge and diabetes self-management. Patient Educ Couns 1996; 29(1):99-108.
(12) Glasgow RE, Hiss RG, Anderson RM, Friedman NM, Hayward RA, Marrero D et al. Report of the Health Care Delivery Work Group; Behavioral research to the establishment of a chronic disease model for diabetes care. Diabetes Care 2001; 24(1):125-130.
(13) Norris SL, Engelgau MM, Narayan KM. Effectiveness of Self-Management Training in Type 2 Diabetes; A Systematic Review of Randomized Controlled Trials. Diabetes Care 2001; 24(3):561-587.
(14) Anderson L. Health-care communication and selected psychosocial correlates of adherence in diabetes management. Diabets Care 1990; 13:66-77.
(15) Snoek FJ, Skinner TC. Psychological counselling in problematic diabetes: does it help? Diabet Med 2002; 19(4):265-273.
(16) Keers JC, Blaauwwiekel EE, Hania M, Bouma J, Scholten-Jaegers SMHJ, Sanderman R et al. Diabetes rehabilitation: development and first results of a Multidisciplinary Intensive Education Program for patients with

prolonged self-management difficulties. Patient Education and Counseling 2004; 52(2):151-157.
(17) Peyrot M. Behavior change in diabetes education. Diabetes Educ 1999; 25(6 Suppl):62-73.
(18) Anderson RM, Funnell MM, Barr PA, Dedrick RF, Davis WK. Learning to empower patients. Results of professional education program for diabetes educators [published erratum appears in Diabetes Care 1991 Oct;14(10):933]. Diabetes Care 1991; 14(7):584-590.
(19) Funnell MM, Anderson RM, Arnold MS, Barr PA, Donnelly M, Johnson PD et al. Empowerment: an idea whose time has come in diabetes education. Diabetes Educ 1991; 17(1):37-41.
(20) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1997; 18:943-949.
(21) Colagiuri R, Colagiuri S, Naidu V. Can patients set their own educational priorities? Diabetes Res Clin Pract 1995; 30(2):131-136.
(22) Van der Zee KL, Sanderman R, Heyink J. De psychometrische kwaliteiten van de MOS 36-item Short Form Health Survey (SF-36) in een Nederlandse populatie. Tijdschrift voor Sociale Gezondheidszorg 1993; 71:183-191.
(23) Ware JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36) : I. Conceptual framework and item selection. Med Care 1992; 30(6):473-483.
(24) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1997; 18:943-949.
(25) Feste C. A practical look at patient empowerment. Diabetes Care 1992; 15(7):922-925.
(26) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1997; 18:943-949.
(27) Surgenor LJ, Horn J, Hudson SM, Lunt H, Tennent J. Metabolic control and psychological sense of control in women with diabetes mellitus. Alternative considerations of the relationship. J Psychosom Res 2000; 49(4):267-273.
(28) Tillotson LM, Smith MS. Locus of control, social support, and adherence to the diabetes regimen. Diabetes Educ 1996; 22(2):133-139.
(29) Wallston K, Stein M, Smith C. Form C of the MHLC scales: A condition-specific measure of locus of control. Journal of Personality Assessment 1994; Vol 63(3):534-553.
(30) Wallston KA, Wallston BS, DeVellis R. Development of the Multidimensional Health Locus of Control (MHLC) Scales. Health Educ Monogr 1978; 6(2):160-170.

(31) Halfens R. Locus of Control: De beheersingsorientatie in relatie tot ziekte- en gezondheidsgedrag. Limburg University, 1985.
(32) Welch G. Diabetes Coping Measure. In: Bradley C, editor. Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice. Londen: Harwood Academic Publishers, 1994: 400.
(33) Welch G, Dunn SM, Beeney LJ. The ATT39: A measure of psychological adjustment to diabetes. In: Bradley C, editor. Handbook of Psychology and Diabetes. Amsterdam: Harwood academic publishers, 1994: 223-245.
(34) Stevens J. Repeated measures analysis. In: Stevens J, editor. Applied Multivariate Statistics for the Social Sciences. New Jersy: Lawrence Erlbaum Associates, 1996: 450-517.
(35) Glasgow RE, Osteen VL. Evaluating diabetes education. Are we measuring the most important outcomes? Diabetes Care 1992; 15(10):1423-1432.
(36) Glasgow RE, Fisher EB, Anderson BJ, LaGreca A, Marrero D, Johnson SB et al. Behavioral science in diabetes. Contributions and opportunities. Diabetes Care 1999; 22(5):832-843.
(37) Brown SA. Meta-analysis of diabetes patient education research: variations in intervention effects across studies. Res Nurs Health 1992; 15(6):409-419.
(38) Steed L, Cooke D, Newman S. A systematic review of psychosocial outcomes following education, self-management and psychological interventions in diabetes mellitus. Patient Educ Couns 2003; 51(1):5-15.
(39) Funnell MM. Empowerment: New Role for Health Professionals, New Role for Patients. www.idf.org. 2003.
(40) Anderson RM, Funnell MM, Fitzgerald JT, Marrero DG. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. Diabetes Care 2000; 23(6):739-743.
(41) Laaksonen M, Luoto R, Helakorpi S, Uutela A. Associations between health-related behaviors: a 7-year follow-up of adults. Prev Med 2002; 34(2):162-170.
(42) Diabetes Control and Complications Trial Research Group. The Effects of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329(14):977-986.
(43) Diabetes Control and Complications Trial Research Group (DCCT). Lifetime benefits and costs of intensive therapy as practiced in the diabetes control and complications trial. The Diabetes Control and Complications Trial Research Group. JAMA 1996; 276(17):1409-1415.
(44) UKPDS. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. Lancet 1998; 352(9131):837-853.

5

Costs and benefits of a Multidisciplinary Intensive Diabetes Education Programme

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Abstract

Objectives
The aim of this study was to determine the costs and benefits of an intensive diabetes education programme for patients with prolonged self-management problems and to determine inclusion criteria for optimal outcomes.

Methods
Sixty-one participants in a Multidisciplinary Intensive Education Programme (MIEP) were measured before starting the intervention (T0), and at one-year follow-up (T2). Data were obtained concerning glycaemic control (HbA1c), diabetes-related distress (PAID), and costs. Changes over time were analysed, and means at T0 and T2 were compared to a reference group of 230 non-referred consecutive outpatients. The number needed to treat (NNT) (i.e., the number of patients to be treated in order to achieve one successful case), was calculated for different baseline values of HbA1c and PAID, in order to determine optimal inclusion criteria.

Results
Diabetes-related costs decreased significantly, and participants improved significantly in HbA1c and diabetes-related distress following MIEP. The levels of HbA1c and distress observed in the participants reached those of the reference group. The T2 costs remained higher than those of the reference group, but the reduction in costs outweighed the intervention costs. Including patients with baseline HbA1c ≥ 8.0%, PAID scores ≥ 40, or both would improve the NNT to achieve clinically relevant outcomes. Seventy-six percent of the patients in this study met these inclusion criteria.

Conclusions
MIEP is effective in improving glycaemic control and diabetes-related distress for patients with prolonged self-management difficulties. In addition to the immediate cost reduction found in the present study, improved glycaemic control may also reduce future costs of diabetic complications. Stricter inclusion criteria with respect to HbA1c and PAID scores may further improve the programme's efficiency.

5.1 Introduction

Diabetes mellitus is a growing public health issue (1), predominantly due to the growing prevalence of Type 2 diabetes and, to a lesser extent, the increasing prevalence of Type 1 diabetes (2). Diabetes requires a complex and demanding treatment and behavioural regimen (3) and generates high direct and indirect medical costs (4). In both Type 1 and Type 2 diabetes, poor glycaemic control resulting in prolonged high blood glucose levels (as measured by glycated haemoglobin: HbA1c) is strongly related to the development of diabetic complications (5;6), such as retinopathy, neuropathy, and cardiovascular disease. These complications are associated with high medical costs (7), disability, and a reduction in quality of life (7-9).

Maintaining acceptable blood-glucose levels depends largely on self-management, which requires daily and life-long efforts from patients. They must inject insulin or take blood-glucose-lowering tablets, follow a healthy and regular diet, exercise regularly and, above all, balance these elements in any possible situation. For example, stress influences insulin sensitivity and blood glucose levels (10), requiring adjustments in self-management. In addition to avoiding high blood-glucose levels in order to prevent long-term diabetic complications, the occurrence of hypoglycaemia (low blood glucose levels) causes several immediate inconvenient effects, ranging from dizziness to coma. Hypoglycaemia can be a serious barrier to self-management (11), complicated by the fact that tight glycaemic control increases the number of hypoglycaemic episodes (6). Given the heavy demands diabetes puts on patients, it is not surprising that many diabetic patients have difficulty maintaining adequate self-management, a problem that manifests itself in poor glycaemic control (12;13) and psychosocial distress (14-17).

Interventions to improve glycaemic control may help prevent long-term complications, thereby leading to long-term cost savings that may outweigh the costs of intervention (7;18;19). The investment costs and postponed benefits, however, can present a major barrier to the implementation of such interventions (20), although several intervention studies have shown more immediate cost reductions. Testa and colleagues (21) conducted a medical intervention that resulted in improved glycaemic control, which led to beneficial labor-related outcomes and fewer ambulatory care visits, as compared to a placebo group. Some studies have shown that lifestyle interventions for diabetic patients can reduce medical costs and are cost-effective within a reasonably short timeframe by reducing the number of hospital admissions and unplanned visits to health care professionals (20;22). Lifestyle interventions conducted in group settings are particularly cost-effective (23).

To support patients with prolonged self-management difficulties, we developed a 12-day outpatient Multidisciplinary Intensive Education Programme (MIEP) (24), based on the empowerment approach (25;26). MIEP

resulted in improved glycaemic control and health-related quality of life (27). Several important elements that have been shown to contribute to the effectiveness of diabetes lifestyle interventions were incorporated into the design of the programme. MIEP goes beyond improving knowledge, because mere knowledge results in neither improved glycaemic control nor behaviour change (28-30), and isolated diabetes educational interventions probably lead only to additional costs (22). To achieve durable changes in self-management, changes in patients' attitudes and motivation are more important than simply improving knowledge (31). Intervention programmes must therefore focus on patients' personal lifestyles, respect individual habits, incorporate social support, and be reinforced over time (32). Treatments that pay attention to both glycaemic and psychosocial factors are likely to be the most effective, and require close collaboration between diabetologists, diabetes nurse specialists, psychologists, and other team members (33). The contents of MIEP will be discussed in more detail in the method section. Such relatively time-consuming and expensive interventions should obviously be reserved for patients who are at particularly high risk and for whom intensive standard care (20;34) (i.e., regular medical check-ups and consultations of a diabetes nurse specialist) is insufficient.

Careful selection of patients and an estimation of the costs relative to effects are needed to optimise the efficiency of MIEP. For this reason, we began by studying the cost-effectiveness of the educational programme by comparing the costs and savings of the intervention. Second, we determined the patients for whom the intervention was most effective in achieving relevant improvements in HbA1c and diabetes-related distress.

5.2 Methods

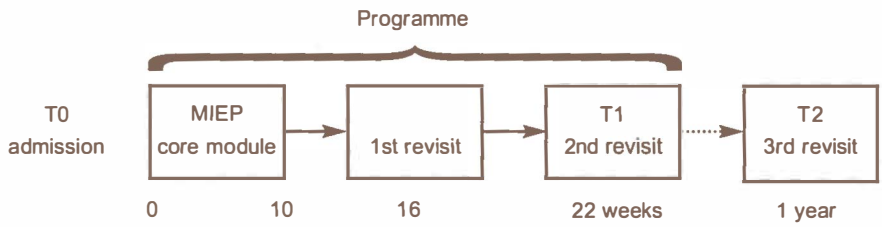
5.2.1 The Multidisciplinary Intensive Education Programme

The Centre for Rehabilitation of the Groningen University Hospital offers a Multidisciplinary Intensive Education Programme (MIEP) for patients with diabetes mellitus with prolonged self-management difficulties, manifested in poor glycaemic control or diabetes-related psychosocial problems. Patients are referred from most outpatient clinics in the region. Figure 1 gives an outline of the programme. MIEP comprises a core module of ten whole days of group sessions (working in fixed groups of six to nine patients) and some individual support over a ten-week period. Follow-up visits take place at six weeks, twelve weeks, and one year after the core module. The one-year follow-up session is not considered to be part of the treatment, because it is used only for receiving and giving feedback, and patients return to regular diabetes care after the second follow-up visit. In effect, participants are withdrawn from their regular outpatient care for a period of five months. The

diabetes education team consists of a diabetes nurse specialist, an endocrinologist, a dietician, a social worker, a psychologist, a physiotherapist, an occupational therapist, and an activity therapist, all of whom work together closely.

The programme aims to empower patients to set and attain their own treatment goals. MIEP highlights a range of diabetes-related topics and has sessions on self-management, diet, exercise, daily activities and employment, psychosocial aspects of diabetes, and behavioural coping strategies. The programme uses a four-phase learning sequence. In the first phase, a topic is introduced, followed by group discussion or practice. In the third phase, patients plan how to incorporate certain aspects into their daily lives, and these plans are evaluated in the fourth phase. Using this approach, the programme is able to take into account the patients' own experiences and the goals that they set upon admission to MIEP. We provided an educational framework covering all relevant topics of diabetes self-management, as education directed solely at patients' own priorities presents a risk of overlooking essential aspects of diabetes self-management (35).

Figure 1: Schedule of the Multidisciplinary Intensive Education Programme



5.2.2 Patients

Of the 80 patients that had admission interviews with MIEP, 11 did not begin or prematurely aborted the programme within the first 3 weeks. HbA1c values were obtained from each of the 69 participants who completed MIEP. Sixty-three patients completed questionnaires at T2, and 56 patients completed cost-questionnaires at both T0 and T2. Using the same exclusion criteria as MIEP, 330 consecutive, non-referred outpatients from the University Hospital Groningen diabetes clinic were asked to serve as a reference group. Seventy percent of these patients (230) gave informed consent, their HbA1c values were obtained, and they completed the same questionnaires as MIEP participants did.

5.2.3 Glycaemic control and diabetes-related distress

Glycaemic control was measured by means of HbA1c, a standard measure in diabetes for the percentage of glycated haemoglobin, indicating glycaemic control in the past 6 to 8 weeks. An HbA1c of ≥ 8.0% is considered to reflect poor glycaemic control (36). The number of episodes of hypoglycaemia during the previous four weeks and the number of severe hypoglycaemic episodes for which assistance was required were obtained through self-reports.

The Problem Areas in Diabetes questionnaire (PAID) (17;37) measured diabetes-related distress. The PAID consists of 20 Likert scale items and has subscales for "diabetes-related emotional problems" (12 items), "treatment-related problems" (3 items), "food-related problems" (3 items), and "social support-related problems" (2 items). The 20 items can be summed to obtain a total diabetes distress score. All scales range from 0 to 100, with higher scores indicating more diabetes-related distress. PAID scores of ≥40 indicate high diabetes-related distress (17).

Statistical testing

The effects of MIEP were determined by comparing means of HbA1c, hypoglycaemia, and PAID scores at baseline and one-year follow-up, using paired samples t-tests. The magnitude of the changes was quantified by calculating effect sizes (ES), which were obtained by dividing the mean change (T2 -T0) by the standard deviation (SD) of that change. Effect sizes of around .20 are considered small, ES of around .50 medium and ES of around .80 are considered large (38). Severe hypoglycaemia was expected to occur in only a relatively small number of patients and to be non-normally distributed. For these reasons, the percentage of patients having 1 or more episode of severe hypoglycaemia was calculated. The results from MIEP participants were compared with those from the reference group of average outpatients at T0 and T2, using independent samples t-tests.

The Number Needed to Treat (NNT), a measure of treatment success, is the number of patients who need to be treated in order to obtain a successful treatment outcome in one case (39;40). The NNT was determined for a clinically relevant improvement in HbA1c and in the total PAID score. The criteria for successful treatment in glycaemic control were a decrease of ≥ 0.5 HbA1c, which is considered clinically relevant (5;39), or a one-year post-treatment HbA1c of < 8.0%, considered fair glycaemic control (36). The criteria for successful treatment in diabetes-related distress were a reduction in PAID scores of one SD of the reference group and a post-treatment score of <40 (non-severe diabetes-related distress, (17)).

The NNT for subgroups with HbA1c ≥ 7.5, ≥ 8.0, ≥ 8.5 and ≥ 9.0 and for PAID ≥ 30, PAID ≥ 40 and PAID ≥ 50 were calculated to determine success rates had these different inclusion criteria been applied. In addition, we calculated the NNT for the combined success criteria of a ≥ 0.5% reduction in

HbA1c, one SD improvement in the total PAID score, or both. The NNT was determined for all participants in MIEP and for the subgroup of patients with HbA1c ≥ 8.0%, PAID ≥ 40, or both. The NNT for the combined criteria indicates the ratio of patients who were successfully treated with respect to at least one of the two main outcomes.

5.2.4 Economic evaluation

The aim of the economic evaluation was to assess the costs of MIEP per patient. The economic evaluation was based on data gathered from 69 programme participants and 230 non-participants from the diabetes outpatient department of the Groningen University Hospital. The participants completed cost questionnaires, thus allowing economic evaluation from a limited societal perspective. Both direct medical costs and direct and indirect non-medical costs were included, as described below. In addition to questionnaire data, expert opinions from two experienced diabetologists were obtained regarding time spent on outpatient visits by various disciplines.

Programme costs were calculated on the basis of a programme schedule provided by the rehabilitation centre, detailing the time spent by the various disciplines involved. Programme overhead costs (rooms, cleaning, etc.) were calculated by means of a 35% surcharge on total personnel costs. This was not applied to costs for the use of sports and fitness facilities or for the swimming pool, for which current rental rates were used. An average group size of seven patients was used to calculate the cost per patient.

Costs of hospital admission were calculated on the basis of the actual number of admission days and the recommended Dutch unit price (indexed to price levels of the year 2003) for hospitalisation per day for university hospitals and general hospitals (41). For health-care consumption outside of the hospital, the recommended Dutch unit price for a GP visit was used. For consultation by telephone, one-half of the price of a visit was used. Travel costs were calculated on the basis of distance between postal codes and information on the mode of transportation used by the patients. For the latter, 61 randomly chosen programme participants were interviewed separately. Each of the 230 patients in the reference group also provided this information. The costs of productivity losses were calculated according to the friction cost method, based on data from the questionnaire regarding sick leave. Standard prices from the Dutch guidelines, specified by sex and age, were used.

The costs of following the educational programme were compared to the difference in health-care consumption costs between T0 and T2. For the follow-up period, costs for successful and unsuccessful patients were compared as well. Participants were considered to be withdrawn from regular care while following the programme. The follow-up consisted of two six-month assessments, totalling one year. Because of the short time horizon, discounting was not applied.

Statistical testing of costs
The effects in diabetes-related costs were tested non-parametrically, as the distributions of cost data were skewed. We used Wilcoxon signed rank tests, the non-parametric alternative for the paired samples t-test, to compare pre and post measures of costs for outpatient clinic contacts, general practitioner contacts, hospital admissions, direct non-medical costs, indirect non-medical costs, and total costs. Mann-Whitney tests for two independent samples were used to test differences between the reduction of total costs for patients who were successfully treated by MIEP and those who were not.

5.3 Results

5.3.1 Study sample

Fifty-six of the 69 MIEP participants completed questionnaires at both T0 and T2, resulting in a response rate of 81%. HbA1c values were obtained from all 69 participants at both measurements. Table 1 presents demographic characteristics of the MIEP participants and the 230 outpatients in the reference group. Participants in MIEP had been more recently diagnosed, but this was not considered to influence the results, as none had been newly diagnosed (< 1 year). No other significant demographic differences were found between the participants and the consecutive outpatients.

Table 1: Demographic characteristics of the study population

	MIEP participants (N=69)	**Outpatients (N =230)**
Gender (% male/ female)	49/ 51	46/ 54
Age (years ± SD)	44 (± 13)	48 (± 13)
Type of diabetes (% type 1/ type 2)	63/ 37	68/ 32
Duration of diabetes (years ± SD)	13 (± 11)*	18 (± 13)
Employed (%)	65	55
Living with a partner (%)	78	76

* $p<.05$

5.3.2 Effects of MIEP on glycaemic control, diabetes-related distress and cost parameters

One year after the intervention, the participants in MIEP had improved significantly on most measures for glycaemic control, diabetes distress (Table 2), and medical costs (Table 3). At T0, participants in MIEP had worse glycaemic control and more diabetes-related distress than did the reference

group. One year after the programme, participants did not differ significantly from the reference group in any of these measures.

The costs for hospital admissions and outpatient clinic contacts, and indirect non-medical costs declined considerably for MIEP patients (See Table 3). In total, the costs measured per patient at T2 were € 1469 lower than costs generated in the year prior to MIEP. The non-parametric tests (Wilcoxon signed ranks tests) showed the ranks of the post-MIEP costs to be significantly lower than the pre-MIEP ranks of costs, but the magnitude of the differences in means could not be tested. At both T0 and T2, MIEP participants generated significantly more costs than did the reference group, but the differences in costs became much smaller at T2.

As shown in Table 4, the total costs of MIEP were € 1327, consisting of € 1023 for running the programme and € 304 for travel expenses. The reduction in costs between T0 and T2 compensated for the costs of MIEP.

Table 2: Effects of MIEP: one-year (T2) compared to baseline (T0) and participants at T0 and T2 compared to reference group

	T0[a]	T2[a]	ES[b]	Reference group (N=230)
HbA1c (N=69)	8.5 ± 1.3 **	8.1 ± 1.2	.32**	8.0 ± 1.2
Hypoglycaemia (N in past 4 weeks)	9.3 ± 8.1 **	5.7 ± 5.9	.53***	5.6 ± 6.8
≥1 severe hypoglycaemia (past 4 weeks)	18%	12%	-	14%
PAID (N=56)				
PAID total	38 ± 22 ***	22 ± 15	.81***	25 ± 18
Emotional problems	44 ± 26 ***	25 ± 16	.88***	29 ± 21
Treatment-related problems	28 ± 22 ***	20 ± 17	.40**	20 ± 22
Food-related problems	31 ± 24 ***	21 ± 19	.44**	22 ± 21
Social support-related problems	22 ± 26 **	12 ± 19	.57***	13 ± 21

* p<.05
** p<.01
*** p<.001
a: means compared to the reference group by independent samples t-tests
b: effect sizes calculated by dividing the mean change by the SD of that change, significance of differences between pre and post measurement calculated with paired samples t-tests

Table 3: Average diabetes-related costs per MIEP participant in the year pre-MIEP (T0) and the year post-MIEP (T2)

		T0 (N = 56)	T2 (N = 56)	p-value[a]	Reference group (N=230)
		€	€		€
Outpatient clinic contacts	M ± SD	49 ± 58	29 ± 21	.003	23 ± 21
	Median	27	18		18
	N'	0	0		0
	p-value[b]	<.001	<.001		
Diabetes-related general practitioner contacts	M ± SD	20 ± 43	6 ± 19	.013	9 ± 37
	Median	0	0		0
	N'	34	47		187
	p-value[b]	<.001	.46		
Diabetes-related hospital admissions	M ± SD	1357 ± 4588	718 ± 2994	.035	48 ± 389
	Median	0	0		0
	N'	42	50		224
	p-value[b]	<.001	.006		
Direct non-medical costs (travel-expenses)	M ± SD	23 ± 23	16 ± 12	.002	20 ± 51
	Median	18	12		6
	N'	0	0		0
	p-value[b]	<.001	<.001		
Diabetes-related indirect non-medical costs (friction costs)	M ± SD	1472 ± 4165	929 ± 3452	.15	158 ± 945
	Median	0	0		0
	N'	45	46		206
	p-value[b]	.073	.107		
Total	M ± SD	2991 ± 6174	1522 ± 5021	.001	289 ± 1050
	Median	126	73		55
	N'	0	0		0
	p-value[b]	<.001	.001		

a: Wilcoxon Signed ranks test comparing T2 with T0

b: Mann-Whitney test comparing participants in MIEP with the reference group

N' : number of patients generating no costs

Table 4: Costs of MIEP per participant

	Costs
Group education by MIEP team (personal + 35% overhead costs)	€ 908
Individual counseling	€ 102
Use of facilities	€ 13
Travel expenses	€ 304
Total	**€ 1327**

5.3.3 Number Needed to Treat (NNT)

As shown in Table 5, the NNT for a ≥ 0.5 % HbA1c reduction was 2.88 for all MIEP participants, which means that, in order to realise this target in one patient, it was necessary to treat 2.88 patients. One out of every 2.09 patients had an HbA1c of < 8.0% at T2. One out of every 1.64 patients achieved at least one of the targets. Furthermore, patients with a higher HbA1c at inclusion had lower NNT for the target of ≥ .5 reduction, as shown in Table 5. Fewer patients would achieve an HbA1c < 8.0%, however.

In general, the NNT for PAID scores were lower than for HbA1c targets; a higher percentage of patients achieved the targets in diabetes distress. Overall, one out of every 2.24 patients achieved a reduction of > 1 SD (≥ 18) of the reference group and one out of every 1.19 patients achieved a PAID score <40. Including patients with baseline scores of ≥ 30, ≥ 40 or ≥ 50, respectively, would lead to a substantial decline in the NNT for a > 1 SD reduction without a large increase of the NNT for the < 40 target (see Table 5).

Combining the success criteria for HbA1c and PAID (an improvement of ≥ 0.5 HbA1c or ≥18 points at the overall PAID score or both), an NNT of 1.80 (95% CI = 1.46-2.41) was found for all MIEP participants (i.e., one in every 1.80 patients improved relevantly in at least one of the two main outcomes). Seventy-six percent of the participants had baseline HbA1c ≥ 8.0%, baseline PAID ≥ 40, or both. The NNT for the combined outcome in this subgroup of patients was 1.48 (95% CI = 1.23- 1.95). For a ≥ 0.5 % HbA1c reduction alone, the NNT was 2.38 (95% CI = 1.73 - 3.71), and for ≥18 reduction at the PAID, the NNT was 1.72 (95% CI = 1.37 - 2.38).

5.3.4 NNT and cost reductions

The comparisons of subgroups based on the success criteria for clinically relevant reductions in HbA1c and or diabetes-related distress revealed some interesting associations between clinical outcomes of MIEP and cost reductions, expressed as the mean total costs at T2 minus the mean total costs at T0 (costs mentioned in Table 3). Patients with clinically relevant reductions in HbA1c had a mean reduction in costs of €2144 in the year after MIEP, as compared to €509 for the group of patients that did not achieve this improvement in HbA1c ($p = .30$; Mann-Whitney test). Comparing subgroups of participants who did achieve a ≥1 SD reduction in PAID and those who did not gave similar results: a reduction of €2535 was found for patients with relevant PAID improvement compared to €408 for patients not achieving the target PAID reduction ($p= .088$). Combining the criteria for HbA1c and PAID resulted in a reduction of €2025 for the successfully treated patients and a reduction of €499 for the non-successfully treated patients ($p = .13$). In sum, patients achieving clinically relevant outcomes in HbA1c and PAID had greater, although statistically insignificant, cost reductions than did patients who did not achieve the target HbA1c and PAID outcomes.

Table 5: Number Needed to Treat (NNT) for various inclusion criteria of HbA1c and PAID score.

Inclusion criterion	N (%)	HbA1c		
		<8.0% at T2 (95% CI[a])	≥0.5 reduction (95% CI[a])	<8.0% and/ or ≥0.5 reduction (95% CI[a])
all patients	69 (100)	2.09 (1.66 - 2.81)	2.88 (2.12 - 4.22)	1.64 (1.38 - 2.07)
HbA1c ≥7.5	54 (78)	2.70 (1.95 - 4.13)	2.70 (1.95 - 4.13)	1.86 (1.48 - 2.53)
HbA1c ≥8.0	44 (64)	3.14 (2.10 - 5.39)	2.20 (1.63 - 3.30)	1.91 (1.48 - 2.73)
HbA1c ≥8.5	31 (45)	3.88 (2.23 - 8.53)	1.94 (1.43 - 3.04)	1.94 (1.43 - 3.04)
HbA1c ≥9.0	23 (33)	3.29 (1.88 - 7.68)	1.77 (1.30 - 2.92)	1.77 (1.30 - 2.92)
		PAID		
		<40 at T2 (95% CI[a])	>1 SD* reduction (95% CI[a])	<40 and/ or >1 SD reduction (95% CI[a])
all patients	56 (100)	1.19 (1.08 - 1.40)	2.24 (1.71 - 3.20)	1.08 (1.02 - 1.21)
PAID total ≥30	31 (55)	1.24 (1.08 - 1.60)	1.41 (1.16 - 1.93)	1.07 (1.01 - 1.28)
PAID total ≥40	27 (48)	1.27 (1.09 - 1.70)	1.17 (1.04 - 1.49)	1.08 (1.01- 1.32)
PAID total ≥50	14 (25)	1.40 (1.09 - 2.41)	1.17 (1.01 - 1.77)	1.08 (1.00- 1.53)

* SD of reference group

a: CI = Confidence Interval

5.4 Discussion

The present study has shown a Multidisciplinary Intensive Education Programme to have beneficial effects for patients with prolonged diabetes self-management difficulties one year following treatment. Improvements were found in glycaemic control, as indicated by the reduction in HbA1c, and in diabetes-related distress. These improvements were achieved for reasonable intervention costs that were outweighed by the substantial reduction in costs generated by participants in the year following MIEP.

The high costs generated by MIEP participants in the year before the intervention were substantially reduced, although they remained significantly higher than the costs generated by the reference group. The reduction in costs measured in this study was equal to the costs of the intervention. Because the participants were withdrawn from their regular diabetes care during MIEP, they generated no outpatient clinic costs or direct non-medical costs, and had no hospital admissions during a period of approximately 5 months. The net

costs of MIEP, therefore, were actually lower than €1327, translating into further improvement of the programme's cost-effectiveness. A relatively small proportion of the MIEP participants generated the major part of the costs. The non-parametric tests performed on this skewed data confirmed that the observed differences in mean costs indeed indicated lower diabetes-related costs following treatment.

The present study does not give an exhaustive description of the costs involved in diabetes care, but the most important variable costs in these relatively young diabetic patients without established diabetic complications were measured. We did not measure the costs for materials used for self-testing of blood glucose, although the improved HbA1c in the MIEP participants could suggest an increase in self-testing. In our opinion however, these costs are likely to be relatively low (in comparison to the costs of hospital admissions, for example). Improvements in HbA1c, when sustained over time, can greatly reduce future health care costs by lowering the risk for diabetic complications (5;6).

From an efficiency perspective, the cost-effectiveness of the intervention is not the only matter of concern. The growing prevalence of diabetes (2) places an increasing burden on outpatient diabetes clinics, with some subgroups of patients showing a pattern of increased health care utilisation (42). The target group for MIEP demands a particularly high level of care, requiring more outpatient visits and more hospital admissions than do average outpatients. Secondary to the patient-related benefits, taking over this care for five months represents a considerable temporary relief for the outpatient clinic itself, in addition to the more lasting reductions in the health-care consumption of these patients after MIEP.

In addition to determining the costs and benefits of MIEP, an important aim of the present study was to determine the patients for whom the programme is most effective in achieving clinically relevant improvements in HbA1c and diabetes-related distress. The effects of MIEP on HbA1c and diabetes-related distress were satisfying for the entire group of participants, with one out of less than 3 patients having a ≥ 0.5% reduction in HbA1c and one out of slightly more than 2 patients reporting a decrease of >1 SD at the PAID (diabetes-related distress). Nevertheless, the selection of patients with higher baseline HbA1c and higher baseline distress would lead to lower numbers needed to treat (NNT) to achieve clinically relevant improvements. With respect to HbA1c, selecting patients with HbA1c ≥ 8.0% did result in a considerable reduction in the NNT. Further restriction of inclusion on the basis of HbA1c would not lead to large improvements of MIEP's efficacy on glycaemic control outcomes. Interestingly, the guidelines of the American Diabetes Association define an HbA1c ≥ 8.0% as poor control (36). The NNT for >1 SD reduction in PAID scores declined considerably when selecting patients on baseline scores of ≥ 30 and ≥ 40, respectively, without much increase in NNT for achieving PAID scores < 40. For patients

with high levels of diabetes-related distress, indicated by PAID scores ≥ 40 (17), one out of every 1.17 achieved a > 1 SD reduction, and one out of every 1.27 achieved a PAID score of < 40 at one-year follow-up. Using these two inclusion criteria would further increase MIEP's efficiency without excluding many patients; 76% of the participants had either HbA1c ≥ 8.0% or PAID ≥ 40.

Participants in MIEP who experienced clinically relevant improvements in HbA1c, diabetes-related distress, or both had greater reductions in the diabetes-related costs than did patients who showed no relevant improvement. As shown in Table 5, decreasing the NNT by means of stricter patient selection would therefore not only increase MIEP's effectiveness in improving glycaemic control and diabetes-related distress, but its cost-effectiveness as well. In successfully treated patients, cost reductions more than compensated for the costs of running the programme (€1327), but this was not the case for patients who were not treated successfully.

5.4.1 Policy implications

In conclusion, the present study offers valuable clues for improving outpatient care for diabetic patients with prolonged self-management problems, both from the patients' perspective and from a cost-effectiveness perspective. The postponed cost-reduction of diabetes interventions can present a serious barrier to the implementation of the intervention (20). As with several other interventions (20;21), we found MIEP to be cost-effective within a year, which makes it an attractive intervention for patients with prolonged self-management difficulties. This holds not only for patients with poor glycaemic control (20), but also for patients with diabetes-related distress. In contrast to most other cost-effectiveness studies of diabetes interventions, this study focused not only on the efficacy of the intervention, but also on improving this efficacy by exploring optimal inclusion criteria for MIEP.

The present study has shown MIEP to result in clinically relevant improvements and the costs of the programme to be almost entirely compensated by reduced medical consumption in the year following treatment. The effects for the patient-related outcomes glycaemic control and diabetes-related distress can be enhanced further by selecting patients with either HbA1c ≥ 8.0% or PAID scores ≥ 40. These measures would lead to further reductions in diabetes-related medical and non-medical costs as well. Applying these criteria more strictly in clinical practice could also help to solve another efficiency problem in the utilisation of additional diabetes care for patients with self-management problems: non-referral of patients who are actually in need of additional care. In particular, patients with high levels of diabetes-related distress are not recognised as needing MIEP at the outpatient clinic (43). The present study has shown, however, that MIEP had beneficial effects for these patients as well.

Intensive outpatient programmes can improve diabetes care and relieve the hectic outpatient clinics that are faced with treating a growing number of diabetic patients. In order to achieve these objectives, such programmes must focus on patients with prolonged high levels of diabetes self-management problems and who generate high costs even before experiencing established diabetes complications.

5.5 References

(1) Mandrup PT. Diabetes. BMJ 1998; 316(7139):1221-1225.
(2) International Diabetes Federation. Diabetes e-Atlas. http://www.idf.org/e-atlas . 2003.
(3) Steed L, Cooke D, Newman S. A systematic review of psychosocial outcomes following education, self-management and psychological interventions in diabetes mellitus. Patient Educ Couns 2003; 51(1):5-15.
(4) Niessen LW, Casparie AF. Effecten en Kosten van de Herziene Richtlijnen voor Diabetes (Effects and Costs of the Revised Diabetes Guidelines). 2001. Rotterdam, Instute for Medical Technology Assesment, University of Rotterdam.
(5) Diabetes Control and Complications Trial Research Group. The Effects of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329(14):977-986.
(6) UKPDS. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. Lancet 1998; 352(9131):837-853.
(7) Diabetes Control and Complications Trial Research Group (DCCT). Lifetime benefits and costs of intensive therapy as practiced in the diabetes control and complications trial. The Diabetes Control and Complications Trial Research Group. JAMA 1996; 276(17):1409-1415.
(8) UKPDS. Quality of life in type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control (UKPDS 37). U.K. Prospective Diabetes Study Group. Diabetes Care 2000; 22:1125-1136.
(9) Rubin RR, Peyrot M. Quality of life and diabetes. Diabetes Metab Res Rev 1999; 15:205-218.
(10) Surwit R, van-Tilburg M, Zucker N, McCaskill C, Parekh P, Feinglos M et al. Stress management improves long-term glycemic control in type 2 diabetes. Diabetes Care 2002; 25(1):30-34.
(11) Cox DJ, Gonder FL, Julian DM, Clarke W. Long-term follow-up evaluation of blood glucose awareness training. Diabetes Care 1994; 17(1):1-5.

(12) Dalewitz J, Khan N, Hershey CO. Barriers to control of blood glucose in diabetes mellitus. Am J Med Qual 2000; 15(1):16-25.
(13) Lloyd CE, Wing RR, Orchard TJ, Becker DJ. Psychosocial correlates of glycemic control: the Pittsburgh Epidemiology of Diabetes Complications (EDC) Study. Diabetes Res Clin Pract 1993; 21(2-3):187-195.
(14) Jacobson AM. The psychological care of patients with insulin-dependent diabetes mellitus. N Engl J Med 1996; 334(19):1249-1253.
(15) Macrodimitris SD, Endler NS. Coping, control, and adjustment in Type 2 diabetes. Health Psychol 2001; 20(3):208-216.
(16) Pouwer F, Snoek FJ, van-der-Ploeg HM, Ader HJ, Heine RJ. Monitoring of psychological well-being in outpatients with diabetes: effects on mood, HbA(1c), and the patient's evaluation of the quality of diabetes care: a randomized controlled trial. Diabetes Care 2001; 24(11):1929-1935.
(17) Snoek FJ, Pouwer F, Welch G, Polonsky WH. Diabetes related emotional distress in dutch and U.S. diabetic patients. A cross-cultural validity of the problem areas in diabetes scale. Diabetes Care 2000; 23(9):1305-1309.
(18) Diabetes Control and Complications Trial Research Group (DCCT). Resource utilization and costs of care in the diabetes control and complications trial. Diabetes Care 1995; 18(11):1468-1478.
(19) Trento M, Passera P, Bajardi M, Tomalino M, Grassi G, Borgo E et al. Lifestyle intervention by group care prevents deterioration of Type II diabetes: a 4-year randomized controlled clinical trial. Diabetologia 2002; 45(9):1231-1239.
(20) Sadur CN, Moline N, Costa M, Michalik D, Mendlowitz D, Roller S et al. Diabetes management in a health maintenance organization. Efficacy of care management using cluster visits. Diabetes Care 1999; 22(12):2011-2017.
(21) Testa MA, Simonson DC. Health economic benefits and quality of life during improved glycemic control in patients with type 2 diabetes mellitus: a randomized, controlled, double-blind trial. JAMA 1998; 280(17):1490-1496.
(22) Gozzoli V, Palmer AJ, Brandt A, Spinas GA. Economic and clinical impact of alternative disease management strategies for secondary prevention in type 2 diabetes in the Swiss setting. Swiss Med Wkly 2001; 131(21-22):303-310.
(23) Rickheim P, Weaver T, Flader J, Kendall D. Assessment of group versus individual diabetes education: a randomized study. Diabetes Care 2002; 25(2):269-274.
(24) Keers JC, Blaauwwiekel EE, Hania M, Bouma J, Scholten-Jaegers SMHJ, Sanderman R et al. Diabetes rehabilitation: development and first results of a Multidisciplinary Intensive Education Program for patients with prolonged self-management difficulties. Patient Educ Couns 2004; 52(2):151-157.

(25) Anderson RM, Funnell MM, Carlson A, Saleh-Statin N, Cradock S, Skinner TC. Facilitating Self-care Through Empowerment. In: Snoek FJ, Skinner TC, editors. Psychology in Diabetes Care. Chichester: John Wiley & Sons, LTD, 2000: 69-98.
(26) Funnell MM, Anderson RM, Arnold MS, Barr PA, Donnelly M, Johnson PD et al. Empowerment: an idea whose time has come in diabetes education. Diabetes Educ 1991; 17(1):37-41.
(27) Links TP, Keers JC, Bouma J, Maaten JCter, Gans ROB, Sanderman R et al. Long-term effects of diabetes rehabilitation for patients with prolonged self-management difficulties. Diabetologia 46[Supplement 2]: A422. 2003.
(28) Brown SA. Interventions to promote diabetes self-management: state of the science. Diabetes Educ 1999; 25(6 Suppl):52-61.
(29) Clement S. Diabetes self-management education. Diabetes Care 1995; 18(8):1204-1214.
(30) Coates VE, Boore JR. Knowledge and diabetes self-management. Patient Educ Couns 1996; 29(1):99-108.
(31) Norris SL, Engelgau MM, Narayan KM. Effectiveness of Self-Management Training in Type 2 Diabetes; A Systematic Review of Randomized Controlled Trials. Diabetes Care 2001; 24(3):561-587.
(32) Anderson L. Health-care communication and selected psychosocial correlates of adherence in diabetes management. Diabetes Care 1990; 13:66-77.
(33) Snoek FJ, Skinner TC. Psychological counselling in problematic diabetes: does it help? Diabet Med 2002; 19(4):265-273.
(34) Glasgow RE. A practical model of diabetes management and education. Diabetes Care 1995; 18(1):117-126.
(35) Colagiuri R, Colagiuri S, Naidu V. Can patients set their own educational priorities? Diabetes Res Clin Pract 1995; 30(2):131-136.
(36) American Diabetes Association (ADA). Standards of Medical Care for Patients With Diabetes Mellitus. Diabetes Care 24[Supplement 1]. 2001.
(37) Welch GW, Jacobson AM, Polonsky WH. The Problem Areas in Diabetes Scale. An evaluation of its clinical utility. Diabetes Care 1997; 20(5):760-766.
(38) Cohen J. A power primer. Psychol Bull 1992; 112(1):155-159.
(39) Cook RJ, Sackett DL. The number needed to treat: a clinically useful measure of treatment effect. BMJ 1995; 310(6977):452-454.
(40) Laupacis A, Sackett DL, Roberts RS. An assessment of clinically useful measures of the consequences of treatment. N Engl J Med 1988; 318(26):1728-1733.
(41) Oostenbrink J.B., Koopmanschap MA, Rutten FFH. Handbook for cost studies, methods and guidelines for economic evaluation in health care [Handleiding voor kostenonderzoek: methoden en richtlijnprijzen voor economische evaluaties in de gezondheidszorg]. Amstelveen: PB - College voor zorgverzekeringen, 2000.

(42) El Fakiri F, Foets M, Rijken M. Health care use by diabetic patients in the Netherlands: patterns and predicting factors. Diabetes Res Clin Pract 2003; 61(3):199-209.
(43) Keers JC, Links TP, Bouma J, Gans ROB, Maaten JCt, Wolffenbuttel BHR et al. Do Diabetologists Recognise Self-Management Problems in their Patients? Diabetes Res Clin Pract. In press.

6

Do diabetologists recognise self-management problems in their patients?

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In press as:
Keers JC, Links TP, Bouma J, Gans ROB, Maaten JCter, Wolffenbuttel BHR et al. Do Diabetologists Recognise Self-Management Problems in their Patients? Diabetes Research and Clinical Practice.

Abstract

Objective
The aim of this study was to determine whether diabetologists recognise patients' needs for additional intensive multidisciplinary care due to glycaemic and diabetes-related psychosocial difficulties.

Research design and methods
We compared 114 participants in a diabetes intervention programme with 201 as yet non-referred outpatients, of whom 54 outpatients were considered eligible for the intervention by their diabetologists; thus 147 outpatients were considered non-eligible.

Results
Analysis revealed that the eligible patients had worse glycaemic control but did not distinguish themselves by other parameters. Significantly, 22 (15%) of the 147 non-eligible patients clearly had diabetes distress and could potentially benefit from the intervention.

Conclusions
The results suggest that in regular care, patients' needs with respect to glycaemic control are recognised by their diabetologists, but patients with high psychosocial diabetes-related distress are often overlooked, though they also may be in need of additional care. Integrated monitoring of diabetes-related distress in outpatients could improve this area of diabetes care.

6.1 Introduction

Diabetes self-management is demanding and many patients have difficulties in maintaining adequate self-management, revealed by poor glycaemic control or diabetes-related psychosocial problems (1;2). Guidelines formulated in the St Vincent Declaration (3) state that healthcare providers should not only focus on monitoring medical aspects, i.e. glycaemic control, but also on psychosocial functioning. However, psychosocial functioning is often poorly monitored in standard diabetes care (4). The result is that self-management problems not directly revealed by poor glycaemic control can easily be overlooked. This implies that a number of patients with self-management problems may not receive optimal treatment. Diabetologists are the main practitioners in diabetes care, and are expected to survey patients' needs and to refer them for additional clinical or psychosocial care when necessary.

Depending on their intensity, duration and focus, interventions for patients with self-management difficulties successfully improve glycaemic control, lifestyle behaviours and health-related quality of life (HRQoL) (4-6). However, for these programmes to be truly effective, they have to reach the patients in greatest need of them (7). Using their 'RE-AIM' framework, Glasgow et al. (8) emphasised that intervention studies often primarily focus on efficacy in controlled situations, thereby neglecting other factors contributing to the eventual effect of the intervention in the "real world" (9;10). For example, little research concentrates on the extent to which diabetes interventions reach their target group (9), or whether health care providers in diabetes clinics adequately refer to additional care when available. In this paper we particularly focus on the reach of an intervention programme for patients with prolonged self-management difficulties. The aim of this study is to determine whether diabetologists in daily practice recognise those patients who need additional care on the basis of glycaemic control as well as psychosocial diabetes-related distress.

6.2 Material and methods

6.2.1 Programme

At the Groningen University Hospital, additional diabetes care for patients with prolonged self-management difficulties is offered by means of a Multidisciplinary Intensive Education Programme (MIEP) (11). Inclusion criteria for MIEP are poor HbA1c that could not be improved by optimising medical treatment and/or diabetes-related distress. Exclusion criteria are age <18 or >70 years, pregnancy, or having severe psychiatric or other co-morbidity. MIEP is based on the empowerment approach (12) and aims to empower patients in their self-management in order to improve HbA1c and

diabetes-related psychosocial distress. MIEP is conducted by a multidisciplinary education team and it comprises ten whole days of group sessions and some individual support over a ten-week period. There are three subsequent follow-up sessions. Diabetologists refer patients from outpatient clinics throughout the northern region of the Netherlands and these patients enrol in MIEP after an admission interview with an internist, a diabetes nurse specialist, a dietician and a psychologist from the education team. Participants in MIEP actually enrol in MIEP in two steps: first they are referred by their diabetologist and then they have an admission interview to consider their appropriateness for MIEP. Participants enrol in MIEP on the basis of both psychosocial and glycaemic problems.

6.2.2 Participants and recruitment

We compared two groups of non-referred outpatients with participants in MIEP to study the referral behaviour of diabetologists. After excluding outpatients using the same criteria as MIEP and patients who had already participated in MIEP, 231 consecutive patients from the diabetes outpatient clinic at the Groningen University Hospital participated in the study. All patients gave informed consent and the local ethics committee approved the study.

The diabetologists (N=10; 5-25 years experience in diabetes care) assessed whether they considered their patients eligible for MIEP and gave their rationale for this decision. The diabetologists could be expected to be familiar with MIEP because they work in the same organization, though at different locations. Furthermore, they are informed about MIEP regularly by a newsletter about the study and brochures including the referring guidelines. We repeated this preceding the study. The diabetologists were well acquainted with 201 (87%) of the patients, 54 of whom they considered eligible and 147 non-eligible for MIEP. The two groups of eligible (N=54) and non-eligible (N=147) outpatients were compared with data from 114 participants in MIEP just before they started the programme and before possible self-selection of MIEP participants could have occurred by declining participation. Thirty outpatients who were not assessed for eligibility for MIEP because the diabetologist replaced a colleague, or the patients were new at the clinic, were analysed separately.

6.2.3 Measures and statistical analysis

We assessed glycaemic control with HbA1c (Bio-Rad, 4.0-6.1%; Munich, Germany) and the self-reported number of (severe) hypoglycaemia. HbA1c was determined in the same laboratory for both participants in MIEP and the outpatients. Diabetes-related distress was measured using the Problem Areas in Diabetes scale (PAID) (13;14). The PAID consists of 20 Likert scale items

and has subscales for 'diabetes-related emotional problems', 'treatment-related problems', 'food-related problems', and 'social support-related problems'. A total distress score of all 20 items can also be calculated. Health-related Quality of Life (HRQoL) was measured with the Rand-36 item health survey (15;16), of which we used subscales for 'physical functioning', 'mental health', 'social functioning' and 'vitality'. To determine whether outpatients potentially in need of MIEP had been overlooked, we calculated percentages of non-eligible patients with poor glycaemic control (HbA1c ≥ 9.0%) and high diabetes-related distress (PAID ≥ 40) (13).
We used ANOVA analyses with Bonferroni post-hoc tests to compare the three groups. Logistic regression analysis indicated which patient characteristics predicted the physicians' decision to consider patients eligible for MIEP.

6.3 Results

The diabetologists considered 54 (27%) outpatients eligible for MIEP because of poor glycaemic control (N = 31), psychosocial problems (N = 8), or a combination of both (N = 15). One hundred and forty-seven (73%) patients were considered non-eligible, because of not meeting inclusion criteria (N = 121), MIEP does not fit into the patient's personal situation (N = 10), lack of motivation (N = 8) or other treatment preferred (N = 8). Table 1 shows that both participants and eligible outpatients were younger, had higher HbA1c and indicated worse social functioning than non-eligible patients did. As expected, participants in MIEP scored worse than the non-eligible outpatients on all four PAID subscales and its total score, and also on the Rand-36 subscales for vitality and mental health, but eligible and non-eligible patients did not differ on these variables. Besides social functioning, eligible patients did not distinguish themselves by psychosocial functioning.

Logistic regression analysis showed that the diabetologists' decision was predicted (Chi2 = 45.9, $p < .001$) by respectively HbA1c (Exp (B) = 2.42, $p < .001$), age (Exp (B) = .97, $p = .027$) and social functioning (Exp (B) = 0.98, $p = .010$). Patients with higher HbA1c, younger age and worse social functioning were more likely to be considered eligible for MIEP. The Odds Ratios (Exp (B)) for age and social functioning were statistically significant but nevertheless very close to one, indicating no clinically relevant effect of these variables in considering additional diabetes care. These findings are in accordance with the physicians' own rationale; poor glycaemic control was their main reason for considering MIEP.

Thirty-three (22%) of the non-eligible patients showed either poor glycaemic control and/or high diabetes-related distress (see Table 1). Significantly, in 29 of these patients their diabetologists did not give a rationale (e.g. unmotivated) for not considering referral and these patients could be considered overlooked. Seven of these non-eligible outpatients had

HbA1c ≥ 9.0%. However, 20 of the non-eligible outpatients with HbA1c < 9.0% had high diabetes-related distress and another 2 had HbA1c ≥ 9.0% combined with high distress. It should be mentioned that only 8 patients were considered eligible because of exclusively diabetes-related psychosocial problems, though MIEP is particularly suitable for distressed patients. Of the 30 outpatients not assessed by a diabetologist, 9 (30%) could be considered eligible for MIEP. Three of these patients had HbA1c ≥ 9.0%, 4 had PAID ≥ 40 but acceptable HbA1c, and 2 had PAID ≥ 40 combined with poor glycaemic control.

Table 1: Comparison between participants, eligible outpatients and non-eligible outpatients; Mean (SD).

	Participants (N=114)	Eligible outpatients (N=54)	Non-eligible outpatients (N=147)
Age (years)	44.1 (13.1)	44.3 (14.3)	49.0 (12.6)[a/b]
Gender (% f/ m)	52/ 48	54/ 46	54/ 46
Type of diabetes (% 1/2)	64/ 36	67/ 33	69/ 31
Duration of diabetes (years)	13.1 (10.9)	17.7 (12.5)[a]	18.9 (13.3)[a]
HbA1c (%)/% HbA1c ≥ 9.0%	8.4 (1.3)/33%	8.8 (1.5)/46%	7.7 (1.0)[a/b]/6%
Hypoglycaemia (N/4 weeks)	7.7 (7.4)	6.2 (6.4)	5.5 (7.2)
Severe hypoglycaemia (% 0 times in previous four weeks)	84%	77%	90%
PAID[1]			
Diabetes-related emotional problems	43 (25)	31 (24)[a]	26 (19)[a]
Treatment-related problems	33 (24)	23 (24)[a]	18 (22)[a]
Food-related problems	33 (23)	27 (23)	20 (20)[a]
Social support-related problems	24 (27)	16 (25)	12 (20)[a]
PAID total/% PAID ≥ 40	39 (21)/49%	30 (21)[a]/32%	23 (17)[a]/17%
Rand-36[2]			
Mental health	63 (19)	69 (18)[a]	75 (16)[a]
Vitality	49 (22)	57 (20)[a]	62 (20)[a]
Social functioning	68 (26)	72 (25)	83 (21)[a/b]
Physical functioning	77 (24)	78 (21)	82 (21)

[a]: significant difference with participants ($p < .05$)

[b]: significant difference with potential participants ($p < .05$)

[1]: PAID: range 0-100, with higher scores indicating more diabetes-related distress.

[2]: Rand-36: range 0-100, with higher scores indicating better HRQoL (4 of the original 9 subscales were used)

6.4 Conclusions

This study clearly illustrates that high HbA1c is the main trigger for physicians when considering additional diabetes care. This conclusion is supported by the proportions of different reasons for considering patients eligible for MIEP, as reported by the diabetologists themselves, and also by patient factors, revealed by logistic regression analysis, that contributed to considering patients eligible or not. Besides poor HbA1c, participants in MIEP selected by the four key members of the multidisciplinary team showed a wider variety of diabetes-related difficulties. It has to be kept in mind that the eligible outpatients were only considered for MIEP. This data reflects a first step only, and when actually referring patients, diabetologists probably pay attention to a wider range of diabetes-related problems. In a second step in the process of referring, it might appear that patients do not need or want additional care, but the first step in noticing difficulties remains essential.

Importantly, the results clearly show that in regular care a considerable number of patients needing additional care are missed in the initial selection for MIEP. Patients with diabetes-related psychosocial distress but with reasonable glycaemic control probably would not receive care for their self-management difficulties. Diabetes-related psychosocial problems are not sufficiently recognised as problems that need extra attention. Moreover, some patients were not assessed at all, of whom some were eligible for additional care. A practice implication of this study is that although interventions might have good results in controlled research settings, they will only be effective if they also reach their target group (10) in daily practice.

We acknowledge that the current system of diabetes care (17), with only a few time-limited check-ups a year, offers few opportunities to pay sufficient attention to patients' psychosocial functioning. To improve psychosocial diabetes care, we advise using more integrated screening methods (e.g. Pouwer et al. (18)) in which trained diabetes nurse specialists could play a central role. In addition to medical care, treatment of a demanding disease like diabetes should also pay attention to patient-oriented outcomes. Adequate treatment for diabetic patients with psychosocial problems starts with a good multidimensional diagnosis, an aspect that so far has not received enough attention in either diabetes research or practice.

6.5 References

(1) Dalewitz J, Khan N, Hershey CO. Barriers to control of blood glucose in diabetes mellitus. Am J Med Qual 2000; 15(1):16-25.
(2) Rubin RR, Peyrot M. Psychosocial problems and interventions in diabetes. A review of the literature. Diabetes Care 1992; 15(11):1640-1657.

(3) Bradley C, Gamsu DS. Guidelines for encouraging psychological well-being: report of a Working Group of the World Health Organization Regional Office for Europe and International Diabetes Federation European Region St Vincent Declaration Action Programme for Diabetes. Diabet Med 1994; 11(5):510-516.
(4) Glasgow RE, Fisher EB, Anderson BJ, LaGreca A, Marrero D, Johnson SB et al. Behavioral science in diabetes. Contributions and opportunities. Diabetes Care 1999; 22(5):832-843.
(5) Snoek FJ, Skinner TC. Psychological counselling in problematic diabetes: does it help? Diabet Med 2002; 19(4):265-273.
(6) Norris SL, Engelgau MM, Narayan KM. Effectiveness of Self-Management Training in Type 2 Diabetes; A Systematic Review of Randomized Controlled Trials. Diabetes Care 2001; 24(3):561-587.
(7) Glasgow RE. A practical model of diabetes management and education. Diabetes Care 1995; 18(1):117-126.
(8) Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health 1999; 89(9):1322-1327.
(9) Glasgow RE, Eakin EG. Medical Office-based Interventions. In: Snoek FJ, Skinner TC, editors. Psychology in Diabetes Care. Chichester: John Wiley & Sons, 2000: 141-168.
(10) Toobert DJ, Strycker LA, Glasgow RE, Bagdade JD. If you build it, will they come? Reach and Adoption associated with a comprehensive lifestyle management program for women with type 2 diabetes. Patient Educ Couns 2002; 48(2):99-105.
(11) Keers JC, Blaauwwiekel EE, Hania M, Bouma J, Scholten-Jaegers SMHJ, Sanderman R et al. Diabetes rehabilitation: development and first results of a Multidisciplinary Intensive Education Program for patients with prolonged self-management difficulties. Patient Education and Counseling 2004; 52(2):151-157.
(12) Funnell MM, Anderson RM, Arnold MS, Barr PA, Donnelly M, Johnson PD et al. Empowerment: an idea whose time has come in diabetes education. Diabetes Educ 1991; 17(1):37-41.
(13) Snoek FJ, Pouwer F, Welch G, Polonsky WH. Diabetes related emotional distress in dutch and U.S. diabetic patients. A cross-cultural validity of the problem areas in diabetes scale. Diabetes Care 2000; 23(9):1305-1309.
(14) Welch GW, Jacobson AM, Polonsky WH. The Problem Areas in Diabetes Scale. An evaluation of its clinical utility. Diabetes Care 1997; 20(5):760-766.
(15) Van der Zee K, Sanderman R, Heyink JW, De Haes H. Psychometric qualities of the RAND 36-item Health Survey 1.0: a multidimensional measure of general health status. Int J Behav Med 1996; 3(2):104-122.
(16) Ware JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36) : I. Conceptual framework and item selection. Med Care 1992; 30(6):473-483.

(17) El Fakiri F, Foets M, Rijken M. Health care use by diabetic patients in the Netherlands: patterns and predicting factors. Diabetes Res Clin Pract 2003; 61(3):199-209.
(18) Pouwer F, Snoek FJ, van-der-Ploeg HM, Ader HJ, Heine RJ. Monitoring of psychological well-being in outpatients with diabetes: effects on mood, HbA(1c), and the patient's evaluation of the quality of diabetes care: a randomized controlled trial. Diabetes Care 2001; 24(11):1929-1935.

7

Success in diabetes rehabilitation; no further increment of effects by telephonic booster sessions

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Submitted

Abstract

Aim
The aim of this study was to determine the additional value of telephonic reminders after a multidisciplinary intensive education programme (MIEP) for diabetic patients with prolonged self-management difficulties.

Methods
Patients were asked to participate in four three-monthly telephonic interviews, structured on participants' personal diabetes-related goals. Patients were randomised to receiving calls (N=22) or not (N=27). Twenty-six patients refused to participate. These three groups were compared. Two-hundred-and-thirty-one non-referred outpatients served as a reference group. Glycaemic control, diabetes-related distress and indicators of empowerment (coping and locus of control) were measured.

Results
In general, patients improved in HbA1c, diabetes-related distress and became more empowered to the level of the average outpatients after MIEP. No additional effect of the telephonic reminders was found. The patients who refused to take in the booster sessions had lower diabetes-related distress throughout the study.

Conclusion
Remarkably, no additional effects of the telephonic reminders were found upon the already good results of MIEP. A more intensive follow-up for a well-defined sub-sample of patients could improve efficacy reminders.

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7.1 Introduction

Diabetes Mellitus is an endocrine disorder characterised by elevated blood glucose levels. A strict, life-long medical and behavioural regimen is necessary to achieve close to normal glucose levels in order to prevent diabetic complications, such as retinopathy, neuropathy and cardiovascular disease (1;2). Self-management is the cornerstone of diabetes care, which includes monitoring blood glucose, injecting insulin and adjusting it to needs, keeping a healthy and regular diet, and having sufficient physical exercise.

A considerable number of diabetic patients experience difficulties in maintaining adequate self-management, as manifested in poor glycaemic control (3;4) and psychosocial problems (3-7), and do not gain sufficient benefit from regular care. Additional self-management and psychological interventions can support these patients in optimising glycaemic control and diabetes-related psychosocial distress, but these interventions are only often effective in the short run and consolidation of effects is limited (8). To achieve long term self-management effects, changes in patients' attitudes and motivation are more important than purely improving knowledge (9). Effective diabetes interventions must be individualised to a person's lifestyle, must respect individual habits, incorporate social support and must be reinforced over time (10). Intensive diabetes education programmes often include a form of booster session in order to consolidate effects (8;11). Since in most studies the intervention and the booster sessions were analyzed as one entity or the telephonic contacts were not used as reinforcement (12-15), little is known about the additional value of these boosters.

In order to improve long-term effects of a multidisciplinary intensive education programme (MIEP) (16), we applied structured telephonic interviews aimed at the participants' personal diabetes goals. Without these interviews, MIEP already had positive outcomes in glycaemic control and health-related quality of life (17), but a post-treatment relapse in glycaemic control was found.

The aim of this study is to determine if telephonic reinforcement can support patients retaining improved glycaemic control, decreasing diabetes-related distress and achieving favourable changes indicators of patient empowerment. For this we compared one-year effects of patients randomised to the booster session with those of patients who did not receive these booster calls. Moreover, we compared the one-year effects of these groups participating in the additional study to the effects of patients who refused to participate in the booster. Furthermore, we will elaborate on the practical usefulness of this way of reinforcement.

7.2 Methods

7.2.1 Rehabilitation programme

At the Groningen University Hospital, additional diabetes care for patients with prolonged self-management difficulties is offered by means of a Multidisciplinary Intensive Education Programme (MIEP) (16). Inclusion criteria of MIEP are poor glycaemic control that could not be improved by optimising medical treatment and / or diabetes-related distress. Exclusion criteria are aged <18 or >70 years, being pregnant or having severe psychiatric or other co-morbidity. MIEP is based on the empowerment approach (18) and aims to empower patients in their self-management and in that way improve glycaemic control and diabetes-related psychosocial distress. MIEP comprises 10 whole days of group sessions and some individual support in a ten-week period and has subsequently three follow-up sessions after 6 and 12 weeks and one year.

7.2.2 Procedure of telephonic reminders

Participants were measured at baseline (T0) and 3 months (T1) and 12 months (T2) after MIEP. At three months follow-up, participants of MIEP were referred back to the outpatient clinic. At that moment they were asked to participate in an additional study in which they would receive 4 telephonic booster sessions. After informed consent, the patients were randomised to receiving the calls or not. The telephonic interviews were structured on basis of goals patients set before entering the programme and held by a nurse who was trained in this. In each interview, patients were asked whether they remembered their goals. For each of their goals patients were asked to what extent they succeeded in achieving this and how they were working on it at the time of the interview. The interviewer informed whether patients experienced barriers in achieving their goals, and what actions they had in mind to overcome these obstacles. The interviewer was instructed not to advise on treatment issues other than contacting a healthcare provider of the outpatient clinic.

7.2.3 Participants

Seventy-six patients participated in the study. HbA1c values, a standard measure for glycaemic control, were obtained from all patients and 61 patients completed the questionnaire at all three measurements. Fifty patients agreed to participate in the post-MIEP telephonic intervention, 27 were randomised to receiving the calls and 23 to not receiving the calls. Twenty-six patients refused to participate in the additional interview sessions. So, the following three groups were compared: patients called, patients not called

and 'non-participants'. The non-participants in the telephonic booster sessions did finish the rehabilitation programme though, filled in the one-year questionnaires and their HbA1c were obtained. Reference values were based on a sample of 231 consecutive non-referred outpatients using the same exclusion criteria as MIEP from the diabetes clinic of the Groningen University Hospital. Table 1 shows the demographic characteristics of study participants, which did not differ between the groups except that patients of the reference were more recently diagnosed on average ($p < .05$).

Table 1: Demographic characteristics

	Overall	Patients called	Patients not called	Non-participants	Reference group
	M ± SD/ %	M ± SD/ %	M ± SD/ %	M ± SD/ %	M ± SD/ %
Age	45 ± 12	45 ± 14	45 ± 12	45 ± 12	48 ± 13
Gender (% m/f)	46/ 54	35/ 65	50/ 50	50/ 50	46/ 54
Time since diagnosis	13 ± 11	13 ± 12	12 ± 9	14 ± 12	18 ± 13
Type of diabetes (% type 1/ type 2)	62/ 38	64/ 36	61/ 39	63/ 37	68/ 32
% employed	66	52	59	85	55

7.2.4 Measures and statistical analysis

Glycaemic control was measured by means of HbA1c, measuring the percentage of glycated haemoglobin. An HbA1c of ≥8.0% is considered poor glycaemic control (19). The Problem Areas in Diabetes questionnaire (PAID) (20;21) measured the diabetes-related distress, ranging from 0 to 100 with higher scores indicating more distress. As indicators of empowerment, we used diabetes-specific questionnaires for health locus of control (22;23) and coping (24;25).

To analyse patterns of change over time in glycaemic control and diabetes-related distress, general linear models (GLM) for repeated measures (ANOVA for repeated measures) were applied. Both linear and quadratic trends were calculated (26). Linear trends tested whether patients improved throughout the entire study period. Quadratic trends determined if patients especially improved during the programme and effects levelled off in the follow-up period. T-tests were used to compare the patients randomised to receive calls or to not receiving calls. Patients who gave informed consent for the telephonic contacts and those who did not want to participate were compared with T-tests.

7.3 Results

7.3.1 Effects of MIEP

In general patients improved in HbA1c, diabetes-related distress and became more empowered. Table 2 shows a small relapse in HbA1c post-MIEP, but the PAID scores even further increased between T1 and T2. Overall, participants became more empowered in the course of the study; significant linear trends were found for avoidance coping (p=.025), passive resignation coping (p=.039), chance locus of control (p=.050) and powerful others locus of control (p=.001). At T2, participants reached the levels of the reference group in all outcomes, whereas at T0 participants indicated worse functioning in all these variables.

Table 2: Effects over time as compared to the reference group and subgroups compared.

	Measurement			**Within-subjects contrasts (p-values)**		**Reference value**
	T0 M ± SD	**T1 M ± SD**	**T2 M ± SD**	**Linear trend**	**Quadratic trend**	**M ± SD**
HbA1c						
Total group (N=76)	8.5 ± 1.2	8.0 ± 1.2	8.1 ± 1.2	.003	.001	7.96 ± 1.24
Patients called (N=23)	8.6 ± 1.3	7.8 ± 1.3	8.0 ± 1.4	.005	.001	
Patients not called (N=27)	8.3 ± 1.2	8.1 ± 1.2	8.0 ± 1.1	ns	Ns	
Patient not participating (N=26)	8.5 ± 1.3	8.1 ± 1.0	8.2 ± 1.0	ns	Ns	
PAID						
Total group (N=61)	38 ± 21	26 ± 17	23 ± 15	.001	.039	25 ± 18
Patients called (N=18)	39 ± 23	23 ± 17	23 ± 15	.018	.004	
Patients not called (N=21)	42 ± 21	30 ± 17	27 ± 17	.011	Ns	
Patient not participating (N=22)	32 ± 21	25 ± 19	16 ± 10	.005	ns	

//*** significance of independent samples t-tests with reference group * P <.05, ** p<.01, ***p<.001*

Chi2 of ANOVA indicating significant differences between subgroups at T0, T1 and T2

7.3.2 Effects of the calls

To determine effects of the calls we compared patients who were randomised to the receiving the calls with patients who were not randomised to this condition ('patient called' with 'patients not called'). No significant differences were found in HbA1c, PAID scores or in the indicators of empowerment at the three measurements. However, since the changes during the intervention period in HbA1c and PAID scores differed in these two groups, the total period of the study was taken into account, not only differences between T1 and T2. HbA1c improved in both groups (linear trend: p=.003), and levelled off between T1 and T2 (quadratic trend: p=.001). GLM for repeated measures indicated that patients called more strongly showed a pattern of initial improvement in HbA1c which levelled off post-MIEP (quadratic trend of the interaction effect: p=.038). This effect, however, is mainly due to improvement *before* the calls took place, i.e. during the rehabilitation programme (See Table 2). In both groups, the PAID scores improved (p =.001) which levelled off after MIEP (p=.005) without deteriorating. No differences in these patterns were found between the two groups. Although no effects of the calls were found in outcomes of MIEP, they were helpful for patients to remember their goals; the percentage of patients able to recall their goals increased from 50% at the first contact to 90% at the second and then stabilised.

7.3.3 Patients not participating in the telephonic booster sessions

About one third of the patients did not want to participate in the telephonic follow-up. These patients were more often employed than the patients who did agree to participate in the booster sessions (see Table 1). Furthermore, these non-participants indicated lower levels of diabetes-related distress at T0 (p=.017) and T2 (p=.004) and they had a higher score on diabetes integration coping at T0 (p=.045). In the patients not giving consent, the same patterns of change in HbA1c and PAID scores were found as in patients giving consent; both groups showed similar changes over time (see Table 2).

7.4 Discussion

The results of this study did not show additional value of telephonic reminders after an intensive diabetes rehabilitation programme. Considering the good overall one-year effects in HbA1c and diabetes-related distress and the intensity of MIEP, possible surplus effects of the booster calls could not be shown (27). Furthermore, the possible small effect of the calls may not have been detected because of the rather low number of study participants.

Interestingly, the non-participants had lower diabetes-related distress throughout the study period, had higher baseline integration coping and were more often employed than the participants. Apparently, the informed consent procedure resulted in a self-selected sample of participants who did not consider the calls necessary, besides possible work-related practical problems of planning the calls. In fact, the aim of MIEP was to empower patients making informed choices about self-management issues themselves; patients being able to mobilise support themselves and to consolidate improvements without booster sessions seems a manifestation of empowerment.

Nevertheless, for some patients, relapse after treatment remains a problem, especially with respect to HbA1c. It is important not to neglect this issue of relapse, even though the results generally show good 1-year results of the intervention. The rather non-invasive method to monitor patients' functioning used in this study did not reveal additional effect of the intervention on top of the effects of MIEP, other than number of personal goals remembered. For the patients in diabetes rehabilitation with prolonged and complicated self-management problems, a more intensive form of booster sessions could be more appropriate. Piette et al. (14;28) showed that intensive telephonic contact added to regular care improved self-management behaviour, glycaemic control and psychosocial functioning. Shifting toward more intensive telephonic contacts for a stricter selected group might increase their effectiveness.

Apart from the form of the booster sessions, an important issue is who to offer these booster sessions. By means of self-selection in the current study, the group of non-participants actually showed the best results. These non-participants indicated higher levels of empowerment in comparison to the participants of the booster sessions. This could be an indication to particularly use booster sessions after diabetes rehabilitation in patients with low levels of empowerment, because they can potentially benefit from post-rehabilitation support aimed at attaining self-management goals. Moreover, this group would be most willing to participate in such an intervention. In future research the particular group that will gain from additional booster sessions has to be defined and the optimal form of booster sessions that maximises surplus effects upon the, in general, already good results of MIEP has to be established.

7.5 References

(1) Diabetes Control and Complications Trial Research Group. The Effects of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329(14):977-986.

(2) UKPDS. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group [see comments]. Lancet 1998; 352(9131):837-853.
(3) Dalewitz J, Khan N, Hershey CO. Barriers to control of blood glucose in diabetes mellitus. Am J Med Qual 2000; 15(1):16-25.
(4) Lloyd CE, Dyer PH, Lancashire RJ, Harris T, Daniels JE, Barnett AH. Association between stress and glycemic control in adults with type 1 (insulin-dependent) diabetes. Diabetes Care 1999; 22(8):1278-1283.
(5) Jacobson AM. The psychological care of patients with insulin-dependent diabetes mellitus. N Engl J Med 1996; 334(19):1249-1253.
(6) Rubin RR, Peyrot M. Psychosocial problems and interventions in diabetes. A review of the literature. Diabetes Care 1992; 15(11):1640-1657.
(7) Watkins KW, Connell CM, Fitzgerald JT, Klem L, Hickey T, Ingersoll-Dayton B. Effect of adults' self-regulation of diabetes on quality-of-life outcomes. Diabetes Care 2000; 23(10):1511-1515.
(8) Brown SA. Interventions to promote diabetes self-management: state of the science. Diabetes Educ 1999; 25(6 Suppl):52-61.
(9) Norris SL, Engelgau MM, Narayan KM. Effectiveness of Self-Management Training in Type 2 Diabetes; A Systematic Review of Randomised Controlled Trials. Diabetes Care 2001; 24(3):561-587.
(10) Anderson L. Health-care communication and selected psychosocial correlates of adherence in diabetes management. Diabets Care 1990; 13:66-77.
(11) Brown SA. Meta-analysis of diabetes patient education research: variations in intervention effects across studies. Res Nurs Health 1992; 15(6):409-419.
(12) Hayes JT, Boucher JL, Pronk NP, Gehling E, Spencer M, Waslaski J. The role of the certified diabetes educator in telephone counseling. Diabetes Educ 2001; 27(3):377-386.
(13) Kim HS, Oh JA. Adherence to diabetes control recommendations: impact of nurse telephone calls. J Adv Nurs 2003; 44(3):256-261.
(14) Piette JD, Weinberger M, McPhee SJ. The effect of automated calls with telephone nurse follow-up on patient-centered outcomes of diabetes care: a randomised, controlled trial. Med Care 2000; 38(2):218-230.
(15) Piette JD, Weinberger M, Kraemer FB, McPhee SJ. Impact of automated calls with nurse follow-up on diabetes treatment outcomes in a Department of Veterans Affairs Health Care System: a randomised controlled trial. Diabetes Care 2001; 24(2):202-208.
(16) Keers JC, Blaauwwiekel EE, Hania M, Bouma J, Scholten-Jaegers SMHJ, Sanderman R et al. Diabetes rehabilitation: development and first results of a Multidisciplinary Intensive Education Program for patients with prolonged self-management difficulties. Patient Education and Counseling 2004; 52(2):151-157.

(17) Links TP, Keers JC, Bouma J, Maaten JCt, Gans ROB, Sanderman R et al. Long-term effects of diabetes rehabilitation for patients with prolonged self-management difficulties. Diabetologia 46[Supplement 2], A422. 2003. Ref Type: Abstract
(18) Funnell MM, Anderson RM, Arnold MS, Barr PA, Donnelly M, Johnson PD et al. Empowerment: an idea whose time has come in diabetes education. Diabetes Educ 1991; 17(1):37-41.
(19) American Diabetes Association (ADA). Standards of Medical Care for Patients With Diabetes Mellitus. Diabetes Care 24[Supplement 1]. 2001.
(20) Snoek FJ, Pouwer F, Welch G, Polonsky WH. Diabetes related emotional distress in dutch and U.S. diabetic patients. A cross-cultural validity of the problem areas in diabetes scale. Diabetes Care 2000; 23(9):1305-1309.
(21) Welch GW, Jacobson AM, Polonsky WH. The Problem Areas in Diabetes Scale. An evaluation of its clinical utility. Diabetes Care 1997; 20(5):760-766.
(22) Wallston K, Stein M, Smith C. Form C of the MHLC scales: A condition-specific measure of locus of control. Journal of Personality Assessment 1994; Vol 63(3):534-553.
(23) Wallston KA, Wallston BS, DeVellis R. Development of the Multidimensional Health Locus of Control (MHLC) Scales. Health Educ Monogr 1978; 6(2):160-170.
(24) Welch G. Diabetes Coping Measure. In: Bradley C, editor. Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice. Londen: Harwood Academic Publishers, 1994: 400.
(25) Welch G, Dunn SM, Beeney LJ. The ATT39: A measure of psychological adjustment to diabetes. In: Bradley C, editor. Handbook of Psychology and Diabetes. Amsterdam: Harwood academic publishers, 1994: 223-245.
(26) Stevens J. Repeated measures analysis. In: Stevens J, editor. Applied Multivariate Statistics for the Social Sciences. New Jersy: Lawrence Erlbaum Associates, 1996: 450-517.
(27) Glasgow RE, Toobert DJ, Hampson SE, Strycker LA. Implementation, generalization and long-term results of the "choosing well" diabetes self-management intervention. Patient Educ Couns 2002; 48(2):115-122.
(28) Piette JD, Weinberger M, McPhee SJ, Mah CA, Kraemer FB, Crapo LM. Do automated calls with nurse follow-up improve self-care and glycemic control among vulnerable patients with diabetes? Am J Med 2000; 108(1):20-27.

8

Does spousal overprotection undermine the benefits of diabetes self-management education?

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Submitted

Abstract

Objective
To show that the beneficial effect of self-management education for patients with diabetes is undermined, if the spousal context is incongruous with the empowerment approach, that is if the spouse is perceived to be overprotective.

Research Design and Methods
Seventy-one consecutive patients with a spouse, participating in a Multidisciplinary Intensive Education Programme (MIEP), were assessed on spousal overprotection and three areas of diabetes self-management (i.e., internal locus of control, diabetes-related distress, and HbA1c), on admission to MIEP and three months after the core module of MIEP. Regression analyses tested the independent associations of patients' sex, baseline spousal overprotection, and interaction between sex and spousal overprotection with diabetes self-management at follow-up, after controlling for the baseline value of the dependent variable.

Results
The increase in internal locus of control and decrease in HbA1c was significantly lower in female patients who perceived their spouse to be more rather than less overprotective before they entered MIEP. Also, regardless of sex, patients who perceived their spouse to be rather overprotective at baseline showed a significantly smaller decrease in diabetes-related distress than patients who did not perceive their spouse to be overprotective.

Conclusions
Spousal overprotection predicted improvement in diabetes self-management during MIEP, especially for female patients. These findings suggest that not only the patient, but also the spouse should be targeted in education programmes to optimise their effectiveness, especially for those with an overprotective spouse.

8.1 Introduction

Diabetes Mellitus requires permanent life-style changes and adherence to treatment regimens. The fulfilment of these tasks does not only require skills and knowledge, but also considerable effort and a lot of discipline. Therefore, it is not surprising that a substantial number of patients has difficulty reaching optimal glycaemic control (60%) and a quarter of the patients has poor control (1,2). In addition, patients may develop psychosocial problems as a consequence of the daily stress of living with diabetes (1-5). Patients who appear to underbenefit from regular care and show enduring problems in handling their diabetes, in terms of poor glycaemic control and/or low quality of life, may benefit from additional intensive self-management education.

Diabetes education has been recognised as the foundation of good diabetes management. Since previous research has shown that merely providing (medical) information is not enough to bring about behavioural change and does not appear to improve glycaemic control, the focus moved away from didactic teaching to a more coping-oriented approach (6-9). This means that nowadays, the aim of self-management education is to *empower* patients to take charge of their own diabetes management. This empowerment approach focuses on overcoming attitudinal and motivational barriers, improving self-management skills, and stimulating feelings of control and self-efficacy (10). In general, this approach appears to be promising (9). For example, the Multidisciplinary Intensive Education Programme (MIEP) provided at our rehabilitation centre has been found to be effective in terms of a significant improvement in HbA1c and mental health in patients who showed problems over an extended period of time before entering the programme (11,12).

To empower patients, self-management education programmes are typically targeted on patients exclusively and only sometimes their family members are involved to a small extent (cf. 13). This is unfortunate, because making and maintaining (life-style) changes that are needed for good glycaemic control does not only depend on the patient's knowledge, motivation, and abilities, but also on the patient's family system, especially the spouse (13-17). Fisher et al. mentioned several reasons for paying more attention to family factors in diabetes management (15). First, most of the self-management behaviour takes place within the family or home. Second, the family and particularly the spouse can have an enormous supportive, but also deleterious effect on patient behaviour and well-being. Third, self-care behaviour is often seen as patient behaviour, but often results from the combination of coping efforts of both the patient and the spouse (see also 18).

Previous research has found greater family support, less conflict, and less overinvolvement to be related to better treatment adherence, illness adaptation (15,16,19-22), and glycaemic control (21,23) in adults. Other

studies have shown that overprotective behaviour of the spouse is accompanied by less relationship satisfaction and less control and self-efficacy in patients with chronic disease (24-26). Unfortunately, little is known about the causality of the associations between family and spousal characteristics and diabetes management, owing to the cross-sectional nature of most of the research. One exception is the work of Chesla et al. (20), which revealed that, for example, unresolved couple conflict is associated with a poorer dietary intake one year later. However, family factors did not predict consistently change in several aspects of disease management, including HbA1c, physical activity, and quality of life. These null findings may be due to the rather arbitrary chosen baseline assessment and time interval. There is not much reason to assume that family functioning, which is likely to be quite constant after many years of marriage (mean relationship duration > 20 years), predicts *change* in diabetes management in any random year between one to nine years after diagnosis.

The current study will provide more insight into the causal relationship between a spousal factor, that is, overprotection, and diabetes management outcomes, including internal locus of control, diabetes-related distress, and HbA1c, in the context of our self-management education programme. We expect that the beneficial effects of diabetes education are undermined, if the spousal context is incongruous with the empowerment approach. The spousal context is considered to be incongruous with the empowerment approach, if the spouse is overprotective towards the patient, because overprotection indicates low trust in the patient's coping abilities and self-care behaviour and, consequently, undermines patient's feelings of control. Accordingly, patients who perceive their spouse to be rather overprotective are expected to benefit less from MIEP than patients who do not perceive their spouse to be overprotective. This is expected to be true especially for female patients, because prior research indicates that women are more strongly influenced by marital experiences, spousal characteristics, including spousal behaviour, and their spouse's health condition than are men (27-31). In sum, our hypotheses are:

(1) Patients who perceive their spouse to be more rather than less overprotective at entry of MIEP will show less increase in internal locus of control, especially when these patients are female;
(2) Patients who perceive their spouse to be more rather than less overprotective at entry of MIEP will show less decrease in diabetes-related distress and HbA1c, especially when these patients are female.

8.2 Research Design and Methods

8.2.1 Self-management programme

The Multidisciplinary Intensive Education Programme (MIEP) consists of 10 one-day-a-week sessions and 2 booster sessions 6 and 12 weeks after the core module (11). It aims to empower patients, with prolonged self-management difficulties or diabetes-related distress, to set and attain their own treatment goals. In so doing, MIEP uses a four-phase learning sequence in which a variety of topics is highlighted, including self-monitoring, diet, exercise, foot-care, daily activities and employment, psychosocial aspects of diabetes, and behavioural coping strategies. First a topic is introduced, followed by group discussion or practice in the second phase. In the third phase, patients set goals, plan how to fit in a certain aspect in their daily lives, which are subsequently evaluated in the fourth phase. Groups comprise of six to nine patients and the diabetes education team is interdisciplinary.

8.2.2 Participants and procedure

From March 2001 to August 2003, 138 patients enrolled MIEP, of which 126 (91.3%) completed the baseline assessment (T0). These patients had persistent self-management problems, despite intensive concern in regular diabetes care. Spontaneous improvement for these patients is not very likely, which was supported by their one year pre-MIEP HbA1c values. Patients between 18 and 75 years of age, who did not have severe physical or mental co-morbidity and were in command of the Dutch language, were admitted to MIEP. During the day at which patients had their admission interviews (approximately one week before they started MIEP), time was scheduled to fill out the baseline questionnaire. A follow-up questionnaire was mailed to patients' home address three months after the core module of MIEP (T1). For the current study, we selected a subsample of patients who had a spouse for at least one year, participated at both T0 and T1, and were treated with insulin. Following Trief et al. (16), we included patients with either type 1 or type 2 diabetes, if they were treated with insulin, because regular insulin administration produces unique challenges. From a psychological and behavioural perspective, insulin treatment is an important factor in the adaptation process and has considerable consequences for quality of life. Since diabetes type is a major dichotomy from a medical perspective, we will test it for inclusion as a control variable in our analyses.

8.2.3 Measures

All variables under study were measured at both T0 and T1. *Overprotection* was measured with six items constructed by Buunk et al. (32). The items

include, for example, "My partner continuously keeps an eye on me" and "When it comes down to it, my partner seems to think that I don't know what's right for me" (see also, 24,25). The answer alternatives ranged from 1 (*never*) to 5 (*very often*) and a sum score within subjects was calculated. The internal consistency was satisfactory (Cronbach's α = .74 and .72 at T0 and T1, respectively).

Internal locus of control was measured with a subscale of the health locus of control scale developed by Wallston et al. (33,34). This subscale measures the extent to which patients perceive their diabetes control to be dependent on their own behaviour. It consists of six items with 6-point agree-disagree Likert-scales. The item scores were summed into a single score (theoretical range: 6 to 36), with higher scores indicating a stronger internal locus of control. Cronbach's α was .70 and .77 at T0 and T1, respectively.

The Problem Areas In Diabetes (PAID) scale was used to assess *diabetes-related distress* (35,36). The PAID consists of 20 items about diabetes-related emotional problems (12 items), treatment-related problems (3 items), food-related problems (3 items), and social support-related problems (2 items). The answer alternatives ranged from 0 (*not at all a problem*) to 4 (*a big problem*). The 20 items were summed into one diabetes-related distress score. This sum score was transformed to a scale ranging from 0 to 100, with a higher score indicating more distress (α was .93 and .94 at T0 and T1, respectively).

Glycaemic control was assessed by means of HbA1c (Biorad, HPLC, Munich: 4.3-6.1%).

8.2.4 Data analyses

Linear regression analyses were performed to determine whether the intended increase in internal locus of control and the intended decreases in diabetes-related distress and HbA1c were related to perceived spousal overprotection at baseline, possibly in interaction with sex. First, age, education, relationship duration, diabetes type, and diabetes duration were tested for inclusion as control variables. In the first step of the regression analyses, the baseline value of the outcome variable and control variables, if necessary, were entered. Next, sex, overprotection, and the interaction between sex and overprotection were entered in consecutive steps. The multiplicative function was computed as the product of a dummy variable (sex: -1 = male, 1 = female) and the "centred" (i.e., deviation from the mean) scores on overprotection (37). Significant interactions were plotted to interpret whether the effects were consistent with the hypotheses (i.e., stronger links between overprotection and improvement in locus of control, diabetes-related distress, and HbA1c for females as compared to males). More specifically, as suggested by Aiken and West (37), we calculated and plotted the regression slopes for female and male patients, separately.

8.3 Results

8.3.1 Patient characteristics

Of the 98 MIEP participants who had a spouse and were treated with insulin, 71 patients (72%) participated at both T0 and T1. T-tests revealed that patients were more likely to drop-out of the study when they perceived their spouse to be more overprotective [t(93) = 2.25, $p < .05$; $M = 13.50 \pm 4.44$ versus $M = 11.38 \pm 3.98$] and when they perceived more internal control [t(92) = 2.25, $p < .05$; $M = 22.05 \pm 4.89$ versus $M = 19.60 \pm 4.63$] at baseline. Glycaemic control [t(85) = -0.55], diabetes-related distress [t(93) = 0.30], and demographic [age: t(92) = -1.21; sex: $Chi^2(1) = 1.74$; education: t(63) = 0.76; relationship duration: t(93) = -0.54] and medical variables [diabetes type: $Chi^2(1) = 0$; diabetes duration: t(92) = -0.97] were not related to drop-out (all *ps* >.10).

The sample consisted of 34 male and 37 female patients with a mean age of 45.1 years (± 10.7). Most of the participants were married (76%), another 18% was cohabiting with their spouse and 6% had a spouse, but did not share a household together. The mean relationship duration was 19.8 years (± 10.8, range: 1 to 41 years). Measured on an 8-point scale ranging from 1 (*primary school*) to 8 (*university degree*), on average, the education of patients was 4.66 ± 1.97. On average, patients with type 1 diabetes (68% of the sample) were somewhat younger and had a longer diabetes duration than patients with type 2 diabetes [age: $M = 41.98 \pm 10.40$ versus $M = 50.37 \pm 8.61$, $t(63) = -3.32$, $p < .01$; diabetes duration: $M = 18.26 \pm 12.99$ versus $M = 11.10 \pm 6.88$, $t(62) = 2.90$, $p < .01$].

8.3.2 Initial analyses

Overall, patients did not perceive their spouses to be very overprotective, but male patients perceived their spouses to be more overprotective than did female patients [$t(69) = 3.18$, $p < 0.01$]. The mean score was 12.97 ± 4.13 for male and 10.14 ± 3.36 for female patients. Furthermore, on a group level, perceptions of spousal overprotection did not change between T0 and T1, for both male [$t(29) = 1.61$] and female patients [$t(33) = 1.41$, *ps* > .10].

Table 1 shows the correlations between the variables in this study, except for diabetes type and sex. Age, education, relationship duration, diabetes type [$t(63) = 0.34$], and diabetes duration were not related (all *ps* > .10) to baseline overprotection. With respect to internal locus of control at T1, a significant relationship was found with sex [$t(60) = 2.13$, $p < .05$], but not with age, education, relationship duration, diabetes type [$t(56) = 0.28$], and diabetes duration (all *ps* > .10). Male patients perceived a stronger internal locus of control than female patients ($M = 21.86 \pm 3.81$ versus $M = 19.44 \pm 5.23$). Demographic and medical variables were not related to diabetes-related distress (all *ps* > .10, except for diabetes type: $t(56) = -1.88$; $p > .05$) and HbA1c

(sex: $t(65) = 1.34$; diabetes type: $t(62) = 0.39$; all $ps > .10$). Thus, except for sex, none of these demographic and medical variables was correlated with both overprotection and one or more of the outcome variables, indicating that these variables do not need to be included as control variables in the regression analyses.

Table 1: Correlations of the initial analyses

	2	3	4	5	6	7	8	9	10	11	12
1 age	.64**	-.21	.14	.05	-.04	-.03	.07	-.04	.05	-.09	.07
2 relationship duration		-.15	.10	.16	-.07	.09	.12	-.04	-.14	-.14	-.05
3 education			.22	-.11	-.04	.16	.01	.06	.22	.16	.03
4 diabetes duration				.14	.04	-.10	.00	-.02	.00	.06	-.14
5 HbA1c (T0)					.52**	.02	.13	-.02	-.04	.21	.14
6 HbA1c (T1)						.16	.19	-.11	-.14	.25*	-.02
7 PAID (T0)							.56**	-.13	-.06	.07	-.13
8 PAID (T1)								.12	-.21	.23	.14
9 Internal LOC (T0)									.29**	.23	.23
10 Internal LOC (T1)										.06	.18
11 Overprotection (T0)											.61**
12 Overprotection (T1)											-

* p <. 05 ** p <.01

8.3.3 Baseline overprotection and changes in diabetes management outcomes

In line with *Hypothesis 1*, changes in internal locus of control were associated with spousal overprotection, but only in female patients (see Table 2). Figure 1 illustrates that female patients showed a smaller increase in locus of control when they reported more rather than less spousal overprotection at baseline.

The results did not reveal an interaction effect between sex and overprotection with respect to diabetes-related distress. Importantly, the results revealed a main effect of baseline overprotection. In partial support of *Hypothesis 2*, regardless of sex, the more patients perceived their spouses to be overprotective, the smaller the decline in distress. The effect of overprotection can be ascribed to emotional and treatment-related problems and not food-related and social support-related problems (results not shown).

In line with *Hypothesis 2*, patients who perceived more rather than less spousal overprotection at baseline showed a smaller decline in HbA1c, but only if the patient was female. For male patients, spousal overprotection was not associated with improvement in HbA1c (Figure 2).

One might assume that an increase in internal locus of control is associated with improvements in diabetes-related distress and HbA1c.

Although a decrease in distress was significantly related to an increase in internal locus of control (r = -.32, p < .05), the association between spousal overprotection and improvement in distress for female patients was not mediated by an increase in internal locus of control. The interactive effects of overprotection and sex on internal locus of control and HbA1c assumed similar forms, however, improvements in both outcome variables were not related (r = -.01, p > .10). Decreases in diabetes-related distress and HbA1c were also unrelated (r = -.08, p > .10).

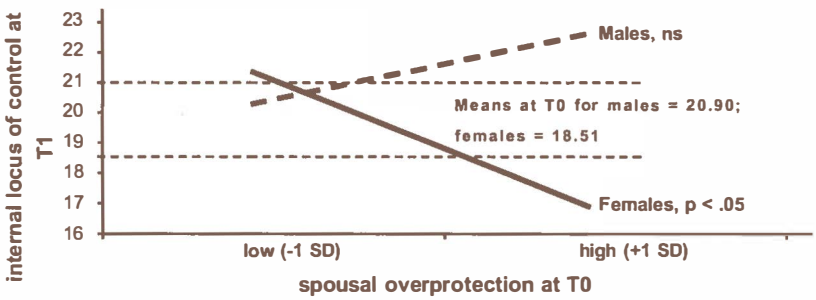

Figure 1: The interactive effect of baseline overprotection and sex on internal locus of control at T1, controlling for baseline internal locus of control.

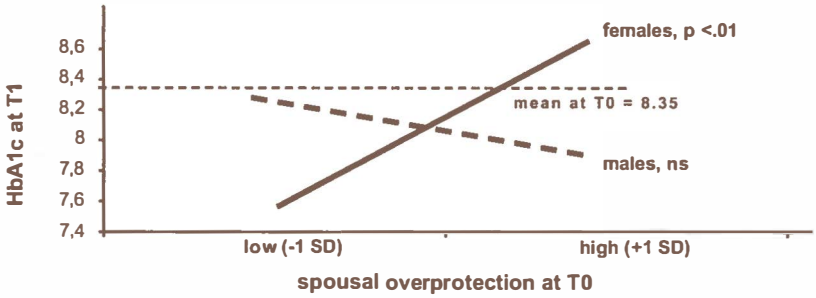

Figure 2: The interactive effect of baseline overprotection and sex on HbA1c at T1, controlling for baseline HbA1c.

Table 2: Results of the Regression of Internal Locus of Control, Diabetes-Related Distress, and HbA1c on Patients' Sex, Spousal Overprotection and Sex by Overprotection, controlling for the baseline value of the outcome variable

	Internal Locus of Control (n = 63)			Diabetes-Related Distress (n = 64)			HbA1c (n = 67)		
Independent Variables	b[a]	ΔR^2	ΔF	b	ΔR^2	ΔF	b	ΔR^2	ΔF
T0 value of the dependent variable	0.31**	.15	10.79*	0.41***	.31	27.81***	0.53***	.27	23.43***
Patients' Sex (S)	-1.05	.03	1.85	7.14	.01	0.45	-0.02	.00	0.39
T0 Spousal Overprotection (O)	-0.19	.02	1.67	1.17*	.06	5.98*	0.05	.02	1.41
S by O	-0.36*	.07	4.90*	-0.03	.00	0.07	0.08**	.08	7.61*

[a] b is the unstandardised regression coefficient in the final model.
* $p < .05$; ** $p < .01$; *** $p < .001$.

8.4 Discussion

Our findings indicate that spousal overprotection undermines the benefits of diabetes self-management education, especially for female patients. In other words, (female) patients appear not to benefit from the education programme, if spousal behaviour is incongruous with the empowerment approach. Noteworthy, spousal overprotection undermined improvement in psychosocial aspects of diabetes management as well as improvement in glycaemic control. More specifically, female patients who perceived their spouse to be more rather than less overprotective before they entered the education programme showed a significantly smaller increase in internal locus of control and a significantly smaller decrease in HbA1c. In addition, regardless of sex, patients who perceived their spouse to be more rather than less overprotective at baseline showed a significantly smaller decrease in diabetes-related distress.

In contrast to our assumption, the associations between spousal overprotection and improvement in glycaemic control and diabetes-related distress were not mediated by improvement in locus of control. This is not that surprising, because some several other studies found non-significant associations between glycaemic control and psychological factors as well (e.g., 38). Furthermore, glycaemic control is strongly influenced by several other

factors, such as the interrelated self-care behaviours, which we did not examine in this study. Since previous research showed that a hostile or conflicted family environment may impede the patient's ability to maintain thoughtful, daily self-care practices (39), improvement in self-care behaviour may be an important mediator of the relationship between spousal overprotection and improvement in glycaemic control. Also, it was found that family relations marked by conflict or hostility may have a direct, negative effect especially on the female patient's physiology, making endocrine balance and subsequent diabetes control more difficult (39). Perhaps, overprotection evokes more distress in female than male patients, resulting in more difficulty for women to improve their glycaemic control.

For the interpretation of our findings, it is important to discuss some limitations of our study. First, although the initial response was very high, a considerable percentage of the participants were lost to follow-up. Because patients who perceived their spouse to be more overprotective and patients who perceived more internal locus of control were more likely to drop-out, the reduced score distribution may have even led to an underestimation of the relationship between spousal overprotection and outcome variables. Second, the sample size is relatively small. Third, we made use of patient-ratings to assess spousal overprotection, which do not necessarily correspond with spouse-ratings or actual spouse behaviour. Indeed, previous research has shown moderate correlations between patients' and spouses' perceptions of spousal overprotection (e.g., 25,26). Our findings indicate that changing spousal behaviour may not be sufficient if the patient still perceives it as overprotective. In that situation increasing the couple's understanding of each other and the patient's evaluation of the behaviour of the spouse may be of equal or even more importance than changing spousal behaviour.

Fisher and Weihs (13), who adopted a social ecological perspective of the management of chronic disease, suggested to shift the focus of intervention from the patient to the social setting in which disease management typically takes place. Unfortunately, although most of the diabetes education programmes do recognize that cognitive and behavioural changes do not only depend on individual characteristics, patients' spouses or other family members are involved in such programmes only to a small extent at best. Importantly, in support of the social ecological perspective, our results indicate that spousal overprotection needs to be addressed in order to optimize the self-management education programme's effectiveness; spousal overprotection can undermine the success of diabetes education, especially for women. Involving spouses may help patients to better integrate disease management skills into their daily life context.

8.5 References

(1) Dalewitz J, Khan N, Hershey CO. Barriers to control of blood glucose in diabetes mellitus. Am J Med Qual 2000; 15(1):16-25.

(2) Gonder-Redenick LA, Cox DJ, Ritterband LM. Diabetes and behavioral medicine: the second decade. J Consult Clin Psychol 2002; 70(3):611-625.

(3) Jacobson AM. The psychological care of patients with insulin-dependent diabetes mellitus. N Engl J Med 1996; 334(19):1249-1253.

(4) Peyrot M, Rubin RR. Levels and risks of depression and anxiety symptomatology among diabetic adults. Diabetes Care 1997; 20(4):585-590.

(5) Watkins KW, Connell CM, Fitzgerald JT, Klem L, Hickey T, Ingersoll-Dayton B. Effect of adults' self-regulation of diabetes on quality-of-life outcomes. Diabetes Care 2000; 23:1511-1515.

(6) Brown SA. Interventions to promote diabetes self-management: state of the science. Diabetes Educ 1999; 25(6 Suppl):52-61.

(7) Clement S. Diabetes self-management education. Diabetes Care 1995; 18(8):1204-1214.

(8) Coates VE, Boore JR. Knowledge and diabetes self-management. Patient Educ Couns 1996; 29(1):99-108.

(9) Glasgow RE, Hiss RG, Anderson EM, Friedman NM, Hayward RA, Marrero D et al. Report of the Health Care Delivery Work Group; Behavioral research to the establishment of a chronic disease model for diabetes care. Diabetes Care 2001; 24(1):124-130.

(10) Snoek FJ, Visser A. Improving quality of life in diabetes: how effective is education? Patient Educ Couns 2003; 51(1):1-3.

(11) Keers JC, Blaauwwiekel EE, Hania M, Bouma J, Scholten-Jaegers SMHJ, Sanderman R et al. Diabetes rehabilitation: development and first results of a Multidisciplinary Intensive Education Program for patients with prolonged self-management difficulties. Patient Educ Couns 2004; 52:151-157.

(12) Links TP, Sluiter WJ, Bouma J, Groen H, Keers JC, Visser R. A Multidisciplinary Education Program (MIEP) for patients with diabetes in daycare in the Academic Rehabilitation Center Beatrixoord. A study on efficiency by the department of Endocrinology (Internal Medicine) in collaboration with Beatrixoord, NCG and MTA-bureau. Groningen: Academic Hospital Groningen, 2003.

(13) Fisher L, Weihs KL. Can addressing family relationships improve outcomes in chronic disease? Report of the National Working Group on family-based interventions in chronic disease. J Fam Pract 2000; 49:561-566.

(14) Fisher L, Chesla CA, Bartz RJ, Gilliss C, Skaff MA, Sabogal F et al. The family and type 2 diabetes: A framework for intervention. Diabetes Educ 1998; 24(5):599-607.

(15) Fisher L, Chesla CA, Skaff MM, Gilliss C, Mullan JT, Bartz RJ et al. The family and disease management in Hispanic and European-American patients with type 2 diabetes. Diabetes Care 2000; 23(3):267-272.
(16) Trief PM, Himes CL, Orendorff R, Weinstock RS. The marital relationship and psychosocial adaptation and glycemic control of individuals with diabetes. Diabetes Care 2001; 24(8):1384-1389.
(17) Trief PM, Sandberg J, Greenberg RP, Graff K, Castronova N, Yoon M et al. Describing support: A qualitative study of couples living with diabetes. Fam Sys Health 2003; 21(1):57-67.
(18) Coyne J, Smith D. Couples coping with a myocardial infarction: Contextual perspective on patient self-efficacy. J Fam Psychol 1994; 8(1):43-54.
(19) Trief PM, Grant W, Elbert K, Weinstock RS. Family environment, glycemic control, and the psychosocial adaptation of adults with diabetes. Diabetes Care 1998; 21(2):241-245.
(20) Chesla A, Fisher L, Skaff MM, Mullan JT, Gilliss CL, Kanter R. Family predictors of disease management over one year in Latino and European American patients with type 2 diabetes. Fam Process 2003; 42(3):375-390.
(21) Schwartz LS, Coulson LR, Toovy D, Lyons JS, Flaherty JA. A biopsychosocial treatment approach to the management of diabetes mellitus. Gen Hosp Psychiatry 1991; 13(1):19-26.
(22) Wearden AJ, Tarrier N, Davies R. Partners' expressed emotion and the control and management of type 1 diabetes in adults. J Psychosom Res 2000; 49(2):125-130.
(23) Cardenas L, Vallbona C, Baker S, Yusim S. Adult onset diabetes mellitus: glycemic control and family function. Am J Med Sci 1987; 293(1):28-33.
(24) Berkhuysen M, Nieuwland W, Buunk BP, Sanderman R, Viersma JW, Rispens P. Effect of high- versus low-frequency exercise training in multidisciplinary cardiac rehabilitation on health-related quality of life. J Cardiopulm Rehabil 1998; 19:22-28.
(25) Hagedoorn M, Kuijer RG, Buunk BP, DeJong GM, Wobbes T, Sanderman R. Marital satisfaction in patients with cancer: Does support from intimate partners benefit those who need it most? Health Psychol 2000; 19(3):274-282.
(26) Kuijer RG, Ybema JF, Buunk BP, de Jong GM, Thijs-Boer F, Sanderman R. Active engagement, protective buffering, and overprotection: Three ways of giving support by intimate partners of patients with cancer. J Soc Clin Psychol 2000; 19(2):256-275.
(27) Acitelli LK, Antonucci TC. Gender differences in the link between marital support and satisfaction in older couples. J Pers Soc Psychol 1994; 67(4):688-698.
(28) Hagedoorn M, Buunk BP, Kuijer RG, Wobbes T, Sanderman R. Couples dealing with cancer: role and gender differences regarding psychological distress and quality of life. Psychooncology 2000; 9(3):232-242.

(29) Hagedoorn M, Sanderman R, Ranchor AV, Brilman EI, Kempen GIJM, Ormel J. Chronic disease in elderly couples: Are women more responsive to their spouses' health condition then men? J Psychosom Res 2001; 51(5):693-696.
(30) McRae JA, Brody CJ. The differential importance of marital experiences for the well-being of women and men: A research note. Soc Sci Res 1989; 18(3):237-248.
(31) Quirouette C, Gold DP. Spousal characteristics as predictors of well-being in older couples. Int J Aging Hum Dev 1992; 34(4):257-269.
(32) Buunk B, Berkhuysen M, Sanderman R, Nieuwland W. Actieve betrokkenheid, beschermend bufferen en overbescherming. Meetinstrumenten voor de rol van de partner bij hartrevalidatie. / The role of the partner in heart disease: Active engagement, protective buffering, and overprotection. Gedrag Gezondheid 1996; 24(6):304-313.
(33) Wallston K, Stein M, Smith C. Form C of the MHLC scales: A condition-specific measure of locus of control. J Pers Assess 1994; 63:534-553.
(34) Wallston KA, Wallston BS, DeVellis R. Development of the multidimensional Health Locus of Control (MHLC) Scales. Health Educ Monogr 1978; 6:160-170.
(35) Snoek FJ, Pouwer F, Welch GW, Polonsky WH. Diabetes-related emotional distress in Dutch and U.S. diabetic patients: cross-cultural validity of the problem areas in diabetes scale. Diabetes Care 2000; 23(9):1305-1309.
(36) Welch GW, Jacobson AM, Polonsky WH. The problem areas in diabetes scale. An evaluation of its clinical utility. Diabetes Care 1997; 20:760-766.
(37) Aiken LS, West SG. Multiple regression: testing and interpreting interactions. 3rd ed. Newbury Park: Sage Publications, 1991.
(38) Coates VE, Boore JR. The influence of psychological factors on the self-management of insulin-dependent diabetes mellitus. J Adv Nurs 1998; 27(3):528-537.
(39) Kiecolt-Glaser JK, Newton TL. Marriage and health: his and hers. Psychol Bull 2001; 127(4):472-503.

9

General Discussion

9 General Discussion

The introduction of this thesis illustrated that diabetes has increasingly become a self-managed disease. The development of new insulin analogues and refined blood-glucose measuring techniques have made it possible for patients to achieve closer to normal glycaemic control and to have more flexibility in their diabetes treatment. However, the knowledge that improved glycaemic control reduces the risk for developing diabetic complications (1;2) has not automatically lead to a massive improvement of treatment outcomes in diabetic patients in general (3;4). The technological developments in diabetes care and the understanding of the importance of glycaemic control does not mean that adaptation to diabetes has become easier. Diabetes self-management requires great, daily lifelong efforts from patients and it is considered one of the most psychologically burdensome diseases (5). Not surprisingly therefore, a considerable number of patients experience diabetes self-management problems, revealed by poor glycaemic control (6;7) and/or diabetes-related psychosocial distress (8;9).

Research has shown that intensive diabetes education, psychological and behavioural interventions can help patients to improve self-management, glycaemic control and well-being (10-12). Most of these effects were found in controlled settings of research and are only partially reproducible in clinical practice. The results of the well known and influential DCCT-study turned out not to be reproducible in the diabetes population at large. The effects could only be achieved in highly motivated participants in a research setting with highly motivated health-care professionals that could intensively support participants (13).

At the outpatient diabetes clinic and the department of diabetes rehabilitation of the Groningen University Hospital it was also noted that a considerable number of patients had prolonged self-management difficulties, despite intensive regular care. For this group of patients, a diabetes rehabilitation programme (Multidisciplinary Intensive Education Programme: MIEP (14)) has been developed. The aim of the study described in this thesis was to determine the effects of MIEP as well as its utilisation in clinical practice. Doing this research within the context of clinical practice had the advantage of studying in a realistic setting and issues with high clinical relevance. At the same time, this research had the disadvantages due to a non-randomised design. Three main research questions were formulated:

- What are the effects of MIEP?
- For whom is MIEP effective?
- Which elements contribute to the effects of MIEP?

In 9.1, the main findings will be summarised and discussed accordingly the three research questions formulated above. The methodological consideration

will be addressed in 9.2. The pros and cons of our study design will be discussed, we will address the measurement of empowerment and self-care and the selection and representativeness of participants will be discussed. Paragraph 9.3 entitled, "Is empowement the way?", actually concerns the theoretical considerations. The usefulness and the practicability of the empowerment approach will be commented on. Then, in 9.4, the findings and organisation of MIEP will be placed into the RE-AIM framework to elaborate on the eventual impact of MIEP in diabetes care. The findings in this thesis provide direct information on some of the domains of this model, while other domains still require additional interpretation. Chapter 9.5 discusses the main implications for practice based on this thesis. Additional to 9.5, future research will be discussed in 9.6.

9.1 Main findings

9.1.1 What are the effects of MIEP?

The effects of MIEP have been studied in several domains, i.e. glycaemic control, health-related quality of life (HR-QoL), diabetes-related distress, indicators of empowerment and cost parameters. In sum, lasting, statistically significant and clinically relevant positive changes were found in glycaemic control, psychosocial variables and costs. These results were particularly satisfying given that the target group of MIEP consists of patients having prolonged self-management difficulties. Interestingly, somewhat different patterns of change were found for HbA1c on the one hand, and HR-QoL and diabetes-related distress on the other hand.

Glycaemic control.
For glycated haemoglobin (HbA1c), we found an effect immediately after the intervention, which levelled off at one-year follow-up. The improvements at three month follow-up ranged from a mean improvement of 0.4% HbA1c in the pilot study to 0.5% HbA1c in the MIEP-1 and the MIEP-2 study (for a description of the studies, see Table 2 in Chapter 1). At one year follow-up the net improvement was 0.4% HbA1c. Both at three and twelve month follow-ups, the participants of MIEP did not differ in mean HbA1c from the reference group of consecutive average outpatients who were not referred to MIEP (MIEP-3). These effects are expressed as means of the whole group of participants. The overall mean changes were especially due to improvement of HbA1c in the patients with baseline values of ≥ 8.0%, whereas the mean of the group with baseline HbA1c values below 8.0% did not change. Probably, the aim of the patients in the latter group would not be to decrease HbA1c. As shown in two large prospective studies (1,2), the reduction of HbA1c in the patient with baseline HbA1c ≥ 8.0%, when consolidated, will greatly reduce the risk of long-term complications.

In defining glycaemic control, not only HbA1c should be considered. Hypoglycaemic episodes are also a matter of concern. In fact, lower mean blood glucose levels increase the risks of having hypoglycaemia (1). Fortunately, this phenomenon was not found in the MIEP study. In the pilot study and MIEP-1, no changes in the number of self-reported hypoglycaemic episodes were found, whereas in the MIEP-2 participants, a decrease in the number of hypoglycaemic episodes was noticed. The relatively small number of patients who experienced severe hypoglycaemic episodes, requiring help from someone else, remained constant at one-year follow-up (MIEP-1) or slightly decreased (MIEP-2). Any decrease in the number of patients having these very disabling severe hypoglycaemia is of clinical importance.

Psychosocial outcomes

Relatively small, but significant, effects were found on several psychosocial outcomes at three month follow-up, which increased at one-year follow up. At three months, participants showed a significant improvement in mental health, but in the same period they indicated a decrease in physical functioning. At one-year follow-up, physical functioning returned to baseline-level and participants further improved in mental health, vitality and social functioning. At one-year follow-up, health-related quality of life was similar in MIEP participants and the reference group of consecutive outpatients. Diabetes-related distress decreased throughout the study period. At baseline, highly elevated levels of diabetes-related distress (15) were found in participants of MIEP, which nearly halved at one-year follow-up and reached the same levels as the reference group.

The participants of MIEP had lower levels of 'powerful others locus of control', 'chance locus of control' and 'passive resignation coping' at one-year follow up compared to baseline, indicating that they had become more empowered. Apparently, MIEP particularly assists patients in reducing the more inadequate patterns, whereas adaptive coping styles and 'internal locus of control' did not increase.

Costs

The above average costs for health care consumption and lost productivity generated by the MIEP participants in the year before the intervention were substantially reduced at one-year follow-up, although these costs remained significantly higher than those of the reference group. The reduction in costs measured in this study equalled the costs of the intervention.

In sum, participants benefited from MIEP, as was evidenced by the improvements in HbA1c and diabetes-related distress (PAID questionnaire). These two measures are a good reflection of the self-management problems in the patients MIEP was designed for. Whereas participants differed clearly from the average outpatients on both outcomes at baseline, no differences

were found at one-year follow-up. MIEP can effectively support patients with prolonged diabetes self-management difficulties to improve HbA1c and diabetes-related distress.

9.1.2 For whom is MIEP effective?

Obviously, MIEP aims to be effective for all patients with prolonged self-management difficulties. However, in order to optimise the efficiency of MIEP as a clinical tool, an effort was made to define the target group that could be expected to experience maximal benefit from MIEP. Patients with poor functioning at baseline, reflected in either HbA1c or HR-QoL, had the greatest improvements in these two main outcomes at one-year follow-up.

Interestingly, women were better able to retain improved HbA1c after MIEP. No post-MIEP relapse was found in women, whereas men on average lost more than half of the short-term improvements at one-year follow-up. Chapter 5 focussed on detecting inclusion criteria that would lead to optimal efficacy of MIEP in terms of the number of patients attaining clinically relevant outcomes in HbA1c and diabetes-related distress and in terms of cost-efficiency. Selection of diabetic patients with a baseline HbA1c $\geq$ 8.0% and/or PAID $\geq$ 40 would further improve MIEP's efficacy without excluding many patients; 76% of the participants matched at least one of these criteria. HbA1c $\geq$ 8.0% and PAID $\geq$ 40 match the criteria for respectively poor glycaemic control (16) and high diabetes-related distress (15). Moreover, patients with clinically relevant improvements in HbA1c or diabetes-related distress had a greater reduction in diabetes-related costs than patients who did not improve.

The question of for whom MIEP is effective, also raises the issue for which patients MIEP would *not* be effective, which preferably should be detectable before the intervention starts. The study described in this thesis was not explicitly designed to focus on this question, nor did the findings provide clear indications that could resolve this issue. A primary goal of MIEP is empowering patients to take responsibility for their diabetes self-management. To a certain extent, this requires patients to be motivated to actively take part in the intervention programme (17) and to be aware of their problematic self-management (18-20). In the current study, certain patients with prolonged self-management problems were excluded from the intervention. For example, depressed patients were considered non-eligible for MIEP, even though depression is highly prevalent in diabetes (21) and is related to poor glycaemic control (22). Moreover, patients were excluded on the basis of an admission interview assessing motivation and eligibility. It would be very interesting to study these non-participating patients, although it would be difficult to include patients who are not motivated to participate in additional diabetes care. When excluding patients, it should be considered that MIEP is often a last option for diabetes care directed at prevention of major complications or a further deterioration of diabetes burnout (23).

In sum, MIEP is especially effective for patients with HbA1c ≥ 8.0% (poor glycaemic control) and/or PAID scores ≥ 40 (high distress). These criteria would provide clear and easy to interpret guidelines for considering referral.

9.1.3 Which determinants contribute to effects of MIEP?

The determinants contributing to the effects of MIEP can be defined as the processes in patients that facilitate improvements in glycaemic control and HR-QoL and they can be defined as the characteristics of the intervention itself. This thesis provides findings that reveal some of the underlying mechanisms of effect of MIEP. However, the fact that MIEP combines many elements that contribute to the efficacy of a diabetes self-management intervention (10;11;24-26), makes it difficult to determine how the separate elements have contributed to the effects. Moreover, it is difficult to select the best predicting determinants of diabetes self-management, because of the very complex nature of this behaviour. In 9.2.1, we will further elaborate on studying a complex multifocus intervention such as MIEP.

Processes

The results suggest that in the short-term (three months), patients HbA1c and HR-QoL improved fairly independently of changes in the indicators of empowerment. However, in order to maintain or to further improve HR-QoL, it is important to consolidate improvements in coping (27) and health locus of control. Changes in HbA1c were only slightly related to changes in diabetes-related coping and diabetes-related health locus of control (28). In 9.2.2, we will further elaborate on the measures and processes that could have explained the improvements in HbA1c. This improvement in HbA1c can be considered an effect of the intervention though, since pre-MIEP HbA1c values illustrated that HbA1c only improved after patients had participated in MIEP, i.e. at three and twelve month follow -ups.

Chapter 8 shows the hampering role of spousal overprotection in diabetes self-management, especially in female patients. Female patients who perceived their spouses to be rather overprotective at baseline of MIEP showed a significantly smaller increase in internal locus of control and a significantly smaller decrease in HbA1c, than female patients who did not perceive their spouse to be rather overprotective. Moreover, regardless of sex, patients who perceived their spouse to be rather overprotective at T1 showed a significantly smaller decrease in diabetes-related distress than patients who did not perceive their spouse to be overprotective.

Programme characteristics

In the introduction of this thesis, we mentioned that the treatment of diabetes requires an empowerment approach as opposed to a compliance based

approach (29;30). Chapter 2 provides insight in the elements of MIEP and how the empowerment approach has been used to develop an intervention programme. An empowerment based intervention should not only target self-care behaviours and medical outcomes, but should also target how patients adapt to living with diabetes, how patients cope with difficult diabetes-related situations and how patients integrate diabetes self-management into their lives.

9.2 Methodological considerations

As mentioned above, the study described in this thesis had some limitations as well, which for example made it difficult to draw conclusions about for whom MIEP is not effective and to draw firm conclusion regarding the mechanisms of effect of MIEP. These limitations are related to the study design used, the measures and the definition and selection of study participants. In the following paragraphs, these issues will be addressed.

9.2.1 Study design

Non-randomised design

Although randomised clinical trials have some limitations as well, they are considered to provide the best clinical evidence and often are the norm in intervention studies. However we chose not to use a randomised design for several reasons. A randomised study requires vast resources, including personnel, time, money, and a sufficient number of study participants. In a randomised study two conditions have to be monitored (either an intervention and care as usual or two forms of an intervention) and only half of the patients referred could be allocated to the experimental intervention, requiring sufficient referrals. Running a randomised clinical trial at the changing and developing department for diabetes rehabilitation was not possible though. Furthermore, there were ethical hesitations to randomise patients to care as usual or to a waiting list while they had prolonged self-management difficulties and an urge for action was felt. A 'second best' solution was chosen in terms of methodological value of the study design to study MIEP, because the research was considered important given the small body of research on intensive diabetes care based on the empowerment approach and because of the virtually absence of studies of outpatient diabetes care in rehabilitation settings.

As a consequence of using a non-randomised design, the findings reported in this thesis may raise some concerns. The longitudinal study design is vulnerable for effects of regression to the mean, i.e. that persons with low baseline scores will improve at follow-up by chance (31). However, it must be noted that the patients included in MIEP had already received

intensive regular care without achieving their treatment goals. Data on HbA1c in the year before participation support this. Moreover, the effects of MIEP were found at both three and twelve month follow-up, which make effects due to regular fluctuations in patients' functioning unlikely. Personal notes of participants do support the conclusion that improvements are due to MIEP. They regularly stated that they wished they had received this form of treatment much earlier and that they had prolonged difficulties over the years which had finally been addressed thoroughly in MIEP.

Multi-focus intervention

The multiple dimensions of diabetes self-management targeted in MIEP that were aggregated into an integrated programme make it hard to detect exactly which aspects of MIEP contributed to the outcomes. This is not a shortcoming of MIEP, but diabetes self-management programmes are by their nature complex and they consist of various interconnected components, which make their evaluation much more complicated than the evaluation of most pharmacological interventions (32). MIEP combines several characteristics that could have contributed to the effects separately or in interaction. Moreover, it is probable that different patients benefited from different elements of MIEP. Literature on diabetes education provides several characteristics that contribute to the effectiveness of an intervention (10;11;24-26). In MIEP all these elements were put together, rather than varying the combinations or using a stepwise approach. The data collected in the present study only allows restricted conclusions about what makes MIEP work.

The intensity of MIEP and the variety of topics related to diabetes self-management might raise the concern that some of the patients would also have been able to achieve their goals with a less intensive intervention. Actually, there would be two ways to study this hypothesis.

The first would be to define participants goals or needs as accurately as possible and then randomise patients either to the entire programme or only to the sessions that are assumed to relate directly to the patients' goals and needs. Probably a separate module aimed at patients defining their diabetes-related goals would need to be developed.

The second way would be to create different forms of MIEP, each of which either contain only a specific element of MIEP, or leave out one specific element. These elements could be defined by their content, e.g. self-control, diet, sports and exercise, or they could be defined by their form, e.g. group or individual treatment, using a learning sequences or not (See also figure 1 in chapter 2). Since there are so many variables in a diabetes-intervention programme, it would be nearly impossible to create a limited number of reasonable variations of MIEP to study in this way. The first option mentioned of studying effects of the whole package of MIEP versus only the elements matching the patients' goals or needs seems more feasible.

For both possibilities, strictly defined and autonomic modules would need to be developed, which can intervene with group education. Targeting only the defined needs could neglect some strengths of MIEP that go beyond simply the parts of MIEP put together. Firstly, the essential characteristic of MIEP as an integrated approach and highlighting the entire spectrum of aspects of self-management would be at least partially lost in the condition where only some modules would be offered. Secondly, MIEP gives patients the chance to compare their own way of adapting to diabetes with others adapting differently. To exemplify, one of the participants of MIEP reported that he started MIEP largely neglecting self-care, whereas one of the other group members was very compulsive in diabetes care. The patient reports to have learnt much from his opposite and how their way of adapting shifted closer in the course of the intervention. To conclude, there are ways to better study the separate elements of MIEP, which can contribute to the theoretical understanding of diabetes education. However, doing so can undermine some of the strengths of MIEP and pay insufficient attention to the complexness of the problems that patients in diabetes rehabilitation are treated for.

9.2.2 Measures

Measurement of empowerment

A main issue in measuring outcomes of MIEP is to define outcomes that reflect patient empowerment. In contrast to outcomes of traditional compliance based diabetes education, much less research on effects of empowerment based interventions has been published and little consensus exists over what variables do measure the concept of patient empowerment. It is important to distinguish between empowerment as an approach (33) and the outcome of this approach in diabetic patients, i.e. 'empowered patients' (34;34). The commonly used outcomes in diabetes research, such as HbA1c and knowledge (35;36) ignore aspects of diabetes self-management considered essential in the empowerment approach (18;34-36). Funnel (18) summed the new roles required of both healthcare professionals and patients of the paradigm-shift from compliance-based to empowerment-based diabetes education. In the empowerment approach the role for patients includes, among other things, to assume responsibility for decision making and outcomes; develop and work towards self-selected goals; and become an active, involved consumer of diabetes care. These roles can be measured to a reasonable good extent. Anderson et al. (34;35) stated that apart from knowledge about diabetes and its treatment, patients need self-awareness about their own values, needs, goals and aspirations regarding diabetes care, in order to make informed decisions in self-management. In an empowerment based intervention this was made operational by measuring diabetes-related self-efficacy and attitudes towards diabetes care (35). Other

intervention studies measured feelings of empowerment by perceived control over diabetes, health locus of control and health beliefs concerning diabetes (37).

In this thesis, diabetes-related health locus of control and diabetes-related coping were used as indicators of patient empowerment. These parameters do probably not exactly meet the parameters used by Anderson et al. (35;38), but do relate to the same concepts. Reviewing the work on empowerment of the past few years, it probably would have been prudent to have added a measure of self-efficacy. However, recently developed measures (38;39) for diabetes-specific self-efficacy were not available when we conducted our study. In one of the first papers on empowerment in diabetes care, Anderson et al. (34) stated that: "the evaluation of a patient education programme based on the empowerment approach should focus on patient achievement of self-selected diabetes care goals". Actually, in reports on empowerment-based intervention, this has not been done. In the MIEP study a simple non-validated one-item retrospective measure was used to determine whether patients achieved their treatment goals in MIEP, in 51% of the participants reported achieving their goals and another 36% reported partial achievement. The development of a reliable and valid instrument to measure self-selected diabetes care goals remains a challenge remains for future studies.

Measurement of self-care behaviour

Self-care behaviours are an important element of diabetes treatment and diabetes education (40). In this thesis, we did not present direct measures of self-care, which could be considered a gap in the evaluation of MIEP and in the explanation of how improvements in glycaemic control were achieved. Adequate self-management in diabetes is difficult to define in specific behavioural components. The basic elements of self-care, medication, diet and exercise, are relatively independent of each other (41). Patients consider dietary aspects of diabetes treatment as most difficult to adhere to, followed by exercise (42;43). Although patients better adhere to taking medication, timing and adjusting medication administration often is a problem (4;44).

The multiple domains of self-care and the absence of reliable, valid and unbiased measures for self-care makes it difficult to determine if estimates of self-care vary as a function of actual behaviour or if they are an artefact of the measurement procedure (45). Some studies found patients performing more self-care behaviours as having better glycaemic control (46) while still other studies did not find such a relationship (47). We did not present data on self-management, because the focus of this thesis concerns empowerment and because simple self-report measures of self-care did not seem to reflect the complex pattern of the interrelated aspects of self-management behaviours.

9.2.3 Participants

There is insufficient insight into the referral and selection of participants for MIEP. In contrast to exclusion criteria, a strictly defined and measurable set of inclusion criteria was not applied. This procedure of referral and admission actually corresponds with the standard way additional diabetes care is delivered in which the diabetologists are expected to refer patients when necessary and the healthcare team of the rehabilitation centre uses an admission interview to determine patients' eligibility for MIEP. This procedure suits clinical practice, but makes it difficult to judge whether the participants are representative and like many studies (48) sufficient information on representativeness of the participants is lacking.

It is unclear to what extent the group of participants does reflect the target group of MIEP, i.e. the population of diabetic patients with prolonged self-management difficulties. No differences were found in demographics and HbA1c in participants in the study and non-participants. Moreover, we did not find great differences in demographics between participants of MIEP and the reference group of average outpatients. Similarly, the patients who prematurely aborted MIEP differed little from patients who finished the programme. There is no evidence to indicate that the participants were not representative, but clear guidelines for detecting patients in need for MIEP can enhance reaching the target group of MIEP. Toobert et al. (49) studied the reach and adoption of an intensive intervention and found a perceived lack of eligible patients to be the main reason for non-referral amongst physicians and a lack of time the main reason amongst patients for refusing to participate. Since MIEP is time-intensive the fact that a lack of time is the main reason for patients not to participate in an intervention (49) is a concern that should be addressed.

The reference group studied and the diabetologists who determined the eligibility of these patients for MIEP all came from the diabetes clinic of the Groningen University Hospital. These diabetologists could be expected to be more familiar with MIEP than their colleagues from other diabetes clinics, because they work in the same organisation as in which MIEP is conducted, although in different departments. It would have been interesting to have studied referral of patients from other hospitals as well.

9.3 Is empowerment the way?

The empowerment approach emphasises the right and responsibility of patients to be the primary decision-maker in their diabetes management (18;33;34;50). Diabetes management has three main characteristics that strongly argue in favour of an empowerment approach and making patients responsible for their self-management (29). Firstly, the most important choices

that affect patients' health and well-being are made by patients themselves, not by health care professionals. Secondly, patients are in control of their diabetes self-management; patients can veto any recommendation of the healthcare team. Thirdly, the consequences of patients' decisions about their diabetes management affect foremost themselves. For most diabetic patients, education based on the empowerment approach is effective in both psychosocial outcomes and glycaemic control (37;51). However, using the empowerment approach in diabetes education raises the question of to what extent patients are able and willing to take responsibility for their diabetes management. Some patients seem incapable of taking responsibility for their diabetes care. Can all diabetic patients make informed decisions about their diabetes? To what extent is the concept of empowerment useful in clinical practice?

There are several barriers to adequate self-management, which might suggest that some patients are just not able to make informed decisions about their diabetes self-management. In discussing these barriers and their consequences for empowerment-based care it is important to distinguish between fixed barriers (predominantly demographic) and variable barriers (predominantly psychosocial). In general, psychosocial factors, such as attitudes, beliefs and perceptions are more important than demographic variables and knowledge about diabetes in self-management behaviour and glycaemic control (6;17;52;53).

However, patients may not be aware of their own role in diabetes-management to provide care to themselves and they might consider the medical team responsible for their diabetes (17). Patients' attitudes and beliefs can change in an empowerment based intervention (54) and these changes were also reported in this thesis. Since these perceptions, which are related to self-care, can be changed, an empowerment approach seems useful. However, empowerment requires certain cognitive abilities of patients and the finding that demographics, like the level of education, do not correlate with self-care in regular diabetes care does not automatically mean that this is also the case in empowerment. Probably, patients with better cognitive functioning or higher education are better able to become an active member in their diabetes care and make informed decisions and thus would benefit most from empowerment based care. This could not be studied thoroughly in the research described in this thesis, since patients who for instance were unable to read and write, or who did not have sufficient knowledge of the Dutch language were excluded from MIEP.

In certain patients it seems self-evident to consider an empowerment approach inappropriate. However, it is very important to be aware that diabetes control can only be achieved by effective self-management (52). Diabetes regulation requires life-long continuous attention, which would be virtually impossible without the patient's cooperation; any kind of self-managed treatment does give decision power to patients. Since strict patient compliance is rare, diabetes care needs, at least partly, an empowerment

approach to facilitate the indispensable self-management. In clinical practice, the choice for either compliance-based diabetes care or empowerment-based care would not be that distinct. In a way, patient empowerment and traditional education are complementary (35;55). Health care providers should not only address the specific concerns of the patients, but also recognise the point at which patients are sufficiently informed about diabetes and its management to identify the possible consequences of the decisions patients make (55). The development of diabetes care and education is an ongoing process, which is not yet finished, and probably never will be finished. From this perspective it is not surprising that there will remain a number of patients who do not achieve their therapeutic goals, who experience high levels of distress and who are poorly regulated.

The empowerment approach in diabetes care better meets the reality of living with diabetes than compliance-based care. MIEP is a way out of prolonged self-management difficulties for many patients but a 100% success rate remains unnattainable. Therefore, the question should not be whether it is perfect, but whether the intervention is an improvement of diabetes care, and if so, how diabetes care can be further improved. MIEP turned out to be an improvement in diabetes care for patients with prolonged self-management difficulties, which should be a trigger for action rather than for contended rest. The current research provided indications of how to optimally utilise MIEP and generated ideas on how to support patients with self-management difficulties. These ideas will be discussed in the next paragraph. The empowerment approach to diabetes education and especially to diabetes rehabilitation is the best option when providing diabetes care, since self-management is the cornerstone of diabetes treatment and empowerment-based interventions improve self-management.

9.4 MIEP and the RE-AIM model

In chapter 1 we introduced the RE-AIM model (13) as a tool to describe and determine the eventual public health impact of an intervention. RE-AIM is an acronym for the five factors that contribute to the impact of an intervention: Reach, Efficacy, Adoption, Implementation and Maintenance. In the following paragraphs we will discuss the findings of this study accordingly the RE-AIM model in order to position the effects and utilisation of MIEP in clinical practice. Glasgow et al. (13;56) proposed weighing the five elements of this framework from 0 to 1, which allows calculating the eventual impact of an intervention ranging from 0 (no impact) to 1 (maximum impact) by multiplying the five factors. In the current research project not all elements could be expressed as a number and so we did not express the impact of MIEP as a number. Fitting the findings of this thesis into the RE-AIM framework helps to determine MIEP's impact for clinical practice.

9.4.1 Reach

For an intensive education programme such as MIEP to be really effective, it has to reach the patients in greatest need of it (25), i.e. the target group. However, little research has concentrated on the extent to which diabetes interventions reach their target group (13;57), or whether health care providers in diabetes clinics adequately refer to additional care when necessary and available (49). MIEP is aimed at patients with self-management difficulties, reflected in both poor glycaemic control and high diabetes-related distress. For optimal utilisation of MIEP it is important to reach all patients who meet this description. In chapter 6, we particularly focussed on the reach of MIEP and studied whether diabetologists in daily practice recognised those patients who needed additional care on the basis of glycaemic control as well as psychosocial diabetes-related distress.

HbA1c was the main trigger for physicians when considering MIEP. This conclusion was supported by the proportions of different reasons for considering patients eligible for MIEP, as reported by the diabetologists themselves and also by patient factors, revealed by logistic regression analysis, that contribute to labelling patients eligible or not. In addition to poor HbA1c, participants in MIEP selected by four key-members of the multidisciplinary team showed a wider variety of diabetes-related difficulties. A considerable number of patients needing additional care were missed in the initial selection of MIEP. Patients having high diabetes-related distress but with reasonable glycaemic control probably do not receive additional care for their self-management difficulties. An important difference between determining poor glycaemic control and diabetes-related distress is that there is a standard measure for glycaemic control available, but for distress there is not. Together with the few time-limited contacts patients have with their health-care providers there is little opportunity to pay sufficient attention to patients' psychosocial functioning. The reach of MIEP thus seems sub-optimal. Chapter 5 hands clues to detect patients with diabetes-related distress more systematically using the PAID questionnaire (15;58).

9.4.2 Efficacy

Evaluating the efficacy of interventions is commonly part of intervention studies. To determine the efficacy of an intervention it is important not only to focus on positive outcomes, but on negative as well (56). In clinical research it is important to study efficacy in health-related quality of life and behavioural outcomes as well (40;56).

Since many intervention studies in diabetes predominantly reported changes in mean scores or effect sizes (10;11;35;59-61), they do not allow determination of a ratio between patients who were treated successfully and patients who were not. Given normally distributed data, the number of

patients attaining certain improvements can be estimated, but additional parameters are helpful in assessing the clinical value of the efficacy of an intervention. Most of our findings on efficacy were traditionally formulated as mean changes (± SD), but we added some parameters (percentages and Numbers Needed to Treat) that could be helpful in evaluating efficacy. In chapter 2, percentages were given of patients achieving clinically relevant improvements in HbA1c and health-related quality of life, patients who stayed relatively stable and patients who deteriorated in these outcomes at three month follow-up. Overall, most patients improved or when having other treatment goals and already having acceptable HbA1c or HR-QoL, they stabilised. A small number of patients deteriorated in HbA1c or mental health despite participating in MIEP. Twelve percent of the patients having baseline HbA1c <8.0% deteriorated more than 0.5% HbA1c. In part, this could be due to the fact that some patients had treatment goals as being less compulsive with self-management or avoiding severe hypoglycaemia. A small number (8%) of all participants deteriorated in mental health. Chapter 5 shows the number of patients to be treated to achieve one successfully treated patient (NNT) (62) in either HbA1c or PAID scores, and how this could be further improved by a stricter inclusion criteria. Putting results into this form turned out to be very useful in determining MIEP's efficacy for clinical practice. Results showed MIEP to be very effective in achieving clinical relevant outcomes in glycaemic control and diabetes-related distress. Efficacy could therefore be termed high.

9.4.3 Adoption

The adoption of an intervention concerns the number and representativeness of health care settings that adopt the intervention (13;57;58). The centre for rehabilitation Beatrixoord is the only centre that runs MIEP. The centre aims to provide intensive additional care for patients with prolonged self-management difficulties from the entire northern region of the Netherlands. From this perspective, the number of clinics using MIEP is not the main issue in determining the adoption, but the number of diabetes outpatient clinics that refer their patients having prolonged self-management difficulties is. The pilot study, which ran in 1997, exclusively included patients from the outpatient diabetes clinic of the Groningen University Hospital. Over the years, patients from an increasing number of clinics have been referred to MIEP. In 1998, 29% of the participants came from hospitals other than the Groningen University Hospital, this increased to 41% in the year 2000 and to 68% in 2002, indicating that adoption is continuously rising. Adoption of the rehabilitation programme by centres in other regions of the Netherlands could further improve care for patients with prolonged self-management difficulties.

9.4.4. Implementation

Intervention studies in diabetes care tend to be performed in settings that maximise internal validity at the expense of external validity (13;56). In the RE-AIM framework, implementation describes the extent to which a programme is delivered as intended. This includes whether participants have fully completed the programme and whether staff members have delivered the intervention as intended. In the current project there was no difference between a controlled, probably non-representative research setting and the 'real world' conditions; MIEP has been developed within the reality and possibilities of current diabetes care, which largely bridges the gap between the theoretical development of the intervention and running it in clinical practice. Since MIEP started, small changes have been made to the programme. These alterations were made between the three studies concerning participants in MIEP. After the pilot study, the five week two days a week schedule was changed into a ten week one day a week programme. In the MIEP-2 study, randomisation to telephonic booster sessions was added to MIEP. The planning of these changes helped to keep the programme as constant as possible during the different studies performed in this project. Moreover, a specific protocol was used which defined the sessions of the programme in terms of its content and which team member delivered it. In this way, stability of the programme was facilitated. In sum, the context in which MIEP was developed and studied facilitated optimal implementation of the programme.

9.4.5 Maintenance

Maintenance concerns the extent to which a programme is sustained over time and can be determined at an individual and an organisational level. As mentioned in 9.2.4, during the period covered in this project, MIEP remained fairly constant, which is important for the organisational level of maintenance. At an individual level, the maintenance of behaviour change is important (13), which is difficult to achieve in diabetes care (10;63). Participants of MIEP consolidated effects until one year after the intervention. Effects in health-related quality of life, in diabetes coping and in locus of control further improved in the 3-12 month post-MIEP period. These effects observed in MIEP's participants, along with the reduction in costs for medical consumption and sick leave that outweigh the costs of the intervention form a major condition to the future maintenance of MIEP. The finding that MIEP is cost-effective within a reasonably short time might be a trigger for healthcare insurance companies to pay for patients participating in MIEP. For further future development of MIEP, maintaining the exact intervention protocol is impracticable, but the empowerment approach used in diabetes rehabilitation should be maintained and possibly further expanded.

9.5 Implications for Practice

For a study as strongly embedded in clinical practice as the MIEP study it is not hard to identify implications for practice. The results showed MIEP to be beneficial for participants. MIEP is an effective treatment to decrease diabetes-related distress, improve health-related quality of life and improve glycaemic control in patients with prolonged self-management difficulties and MIEP is a necessary supplement to regular outpatient diabetes care.

9.5.1 Target group

This thesis provides practical clues for the selection of participants of MIEP. Most patients with self-management problems, as revealed by poor glycaemic control (HbA1c ≥ 8.0%) and/or high diabetes-related distress (PAID ≥ 40), benefit from MIEP. To reach the target group of MIEP, it is important for the department of diabetes rehabilitation to communicate what they offer, for whom MIEP is suitable, and how these patients can be detected. The department of diabetes rehabilitation has already put a lot of effort in communicating the programme to outpatient diabetes clinics. This should be a continuing process in which especially the recognition of eligible patients deserves further attention, which needs a clear definition of the target group as well as guidelines or tools to detect patients in need for additional care (64).

9.5.2 Costs and effects

Postponed cost-reductions of diabetes interventions can be a serious barrier for implementation of the intervention (65). Like a few other interventions (65;66), MIEP is cost-effective within a follow-up of one year, which makes it an attractive intervention for patients with prolonged self-management difficulties. The results presented in chapter 5 show that MIEP results in clinically relevant improvements while the programme costs were almost entirely compensated by reduced medical consumption in the year post-MIEP. Moreover, the improved HbA1c levels will, if sustained over time, reduce the risks for developing diabetic complications (1;2), which are related to high medical costs (67), disability and a reduction in quality of life (67-69). In addition to this already good balance between costs, costs reductions and effects, the costs reductions - effects ratio can be further enhanced by stricter patient selection with either poor glycaemic control or high diabetes-related distress. Doing so, the reduction in diabetes-related medical and non-medical costs will further improve (Chapter 5). Both from the patients' perspective and from a cost-effectiveness perspective, diabetes rehabilitation is a valuable and necessary complement to diabetes care.

9.5.3 Empowerment

Given the good results reported in this thesis using the empowerment approach it is an appropriate moment to consider the contents of the programme in light of the results and theoretical background. It is important to discuss the implications of theoretical developments and research findings to avoid a possible gap between research (this thesis) and practice (the rehabilitation and outpatients setting). It should be discussed how the contemporary empowerment approach to diabetes care can even be more strongly embedded within diabetes rehabilitation, in order to further improve the efficacy of MIEP. For example, detection of patients' goals and needs could receive more attention and be used as a guideline throughout the programme. The telephonic booster sessions did not seem the most appropriate way to facilitate empowerment and self-management after MIEP; the embedding of the approach of MIEP in regular care probably is a better way.

Over the years ideas about diabetes education and management have changed. Patients are acknowledged to play a decisive role in diabetes management and health psychologist and behavioural scientists increasingly contribute to diabetes care and research (26;42). The growing use of terms like 'empowerment' and 'diabetes burnout' by healthcare professionals indicates this shift towards a more psychological view of diabetes. Together with the ongoing medical developments, this is a major pillar of the development of diabetes care.

9.5.4 Spousal overprotectiveness

Most intervention programmes in diabetes recognise that cognitive and behavioural changes do not only depend on individual characteristics of the patient, but also on the social context in which self-management takes place. However, patients' spouses are mostly involved in such programmes to a small extent. Our results suggest that spousal overprotectiveness needs to be addressed in order to optimise the effectiveness of self-management programmes. Involving spouses may help patients to better integrate diabetes self-management into their daily life context.

9.6 Future research

The current study not only provided important data on effects and utilisation of MIEP, but generated several ideas for future research as well. The most feasible directions for future research will be discussed in this chapter.

9.6.1 Randomised clinical trials

In chapter 1.3 and in chapter 9.2.1 we elaborated on the use of randomised trials and compared such a design to the longitudinal design with a non-equivalent control group that we used. Randomised clinical trials (RCTs) are considered the 'golden standard' to evaluate intervention studies. Nevertheless, RCTs are not perfect either. RCTs particularly can have problems with external validity (70) and are often difficult to employ in 'real life' settings in which diabetes care is being provided (57). Randomising patients to either MIEP or to care as usual would not be very useful in view of the already large body of evidence that patient-centred, intensive interventions help patients to improve diabetes self-management, glycaemic control and well-being. Moreover, our results already provided convincing evidence for the efficacy of MIEP. The question of whether patients need the whole package of MIEP or could achieve the same improvements with only part of the programme, i.e. the modules directly related to their needs and goals, remains unanswered. This should be studied in a randomised design and would improve understanding of what makes MIEP work. In fact, we have already begun such a study. Patients with high levels of diabetes-related distress will be randomised to either receiving a few problem-directed additional consultations with a diabetes nurse specialist or participation in MIEP.

3.6.2 Monitoring of outpatients care needs

This next 'MIEP' study also deals with another conclusion of this thesis that requires additional research, namely the fact that recognition of patients in need for additional diabetes care is unsatisfactory. Procedures and tools used to detect and react upon high levels of diabetes-related distress might improve diabetes care, which should not only be focussed on clinical outcomes but also on psychosocial functioning (71). Running this research in hospitals other than the Groningen University Hospital will further improve the clinical and scientific value of the results.

3.6.3 Ongoing role of behavioural science in diabetes

Medical developments have not resulted in a diminishing role of behavioural and psychological determinants in diabetes management. Instead, their role became increasingly important, and the opportunities for behavioural sciences and health psychology rose accordingly (42). Mean HbA1c levels in diabetic patients are far from optimal (6;72), which can be largely attributed to the heavy adaptation and behavioural burden self-management puts upon diabetic patients. Despite the expanding medical knowledge that eventually could lead to curing type 1 diabetes (73-75), finding a cure for type 1 diabetes will probably take many years, so the role of self-management remains

essential. Moreover, nowadays, the consequences of type 2 diabetes are considered to be as serious as those of type 1 diabetes. The largely increasing number of type 2 diabetes worldwide (76;77) requires ongoing efforts of behavioural sciences to study the behavioural and psychological determinants of the pathogenesis and treatment of the disease. In the case of type 2 diabetes, unhealthy lifestyles that have contributed to the development of diabetes are the main foci of interest of treatment as well. It is a huge challenge to help patients to alter these lifestyle patterns that often have existed for a long time. In conclusion, many of challenges for behavioural scientists remain in diabetes research and practice.

9.7 References

(1) Diabetes Control and Complications Trial Research Group. The Effects of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329(14):977-986.

(2) UKPDS. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group [see comments]. Lancet 1998; 352(9131):837-853.

(3) Bernard AM, Anderson L, Cook CB, Phillips LS. What do internal medicine residents need to enhance their diabetes care? Diabetes Care 1999; 22(5):661-666.

(4) Rubin RR, Peyrot M. Implications of the DCCT. Looking beyond tight control. Diabetes Care 1994; 17(3):235-236.

(5) Cox DJ, Gonder FL. Major developments in behavioral diabetes research. J Consult Clin Psychol 1992; 60(4):628-638.

(6) Dalewitz J, Khan N, Hershey CO. Barriers to control of blood glucose in diabetes mellitus. Am J Med Qual 2000; 15(1):16-25.

(7) Lloyd CE, Dyer PH, Lancashire RJ, Harris T, Daniels JE, Barnett AH. Association between stress and glycemic control in adults with type 1 (insulin-dependent) diabetes. Diabetes Care 1999; 22(8):1278-1283.

(8) Jacobson AM. The psychological care of patients with insulin-dependent diabetes mellitus. N Engl J Med 1996; 334(19):1249-1253.

(9) Watkins KW, Connell CM, Fitzgerald JT, Klem L, Hickey T, Ingersoll-Dayton B. Effect of adults' self-regulation of diabetes on quality-of-life outcomes. Diabetes Care 2000; 23(10):1511-1515.

(10) Brown SA. Interventions to promote diabetes self-management: state of the science. Diabetes Educ 1999; 25(6 Suppl):52-61.

(11) Norris SL, Engelgau MM, Narayan KM. Effectiveness of Self-Management Training in Type 2 Diabetes; A Systematic Review of Randomized Controlled Trials. Diabetes Care 2001; 24(3):561-587.

(12) Peyrot M. Behavior change in diabetes education. Diabetes Educ 1999; 25(6 Suppl):62-73.
(13) Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health 1999; 89(9):1322-1327.
(14) Keers JC, Blaauwwiekel EE, Hania M, Bouma J, Scholten-Jaegers SMHJ, Sanderman R et al. Diabetes rehabilitation: development and first results of a Multidisciplinary Intensive Education Program for patients with prolonged self-management difficulties. Patient Education and Counseling 2004; 52(2):151-157.
(15) Snoek FJ, Pouwer F, Welch GW, Polonsky WH. Diabetes-related emotional distress in Dutch and U.S. diabetic patients: cross-cultural validity of the problem areas in diabetes scale. Diabetes Care 2000; 23(9):1305-1309.
(16) American Diabetes Association (ADA). Standards of Medical Care for Patients With Diabetes Mellitus. Diabetes Care 24[Supplement 1]. 2001.
(17) Day JL. Diabetic patient education: determinants of success. Diabetes Metab Res Rev 2000; 16 Suppl 1:S70-S74.
(18) Funnell MM. Empowerment: New Role for Health Professionals, New Role for Patients. www.idf.org. 2003.
(19) de W, I, Visser AP, Kok G, van d, V. Determinants of active self-care behaviour of insulin treated patients with diabetes: implications for diabetes education. Soc Sci Med 1990; 30(5):605-615.
(20) Doherty Y, Hall D, James PT, Roberts SH, Simpson J. Change counselling in diabetes: the development of a training programme for the diabetes team. Patient Educ Couns 2000; 40(3):263-278.
(21) Pouwer F, Beekman AT, Nijpels G, Dekker JM, Snoek FJ, Kostense PJ et al. Rates and risks for co-morbid depression in patients with Type 2 diabetes mellitus: results from a community-based study. Diabetologia 2003; 46(7):892-898.
(22) de-Groot M, Jacobson AM, Samson JA, Welch G. Glycemic control and major depression in patients with type 1 and type 2 diabetes mellitus. J Psychosom Res 1999; 46:425-435.
(23) Polonsky WH. Diabetes Burnout: What to do when you can't take it anymore. 1 ed. Alexandria: American Diabetes Association, 1999.
(24) Anderson L. Health-care communication and selected psychosocial correlates of adherence in diabetes management. Diabets Care 1990; 13:66-77.
(25) Glasgow RE. A practical model of diabetes management and education. Diabetes Care 1995; 18(1):117-126.
(26) Snoek FJ, Skinner TC. Psychological counselling in problematic diabetes: does it help? Diabet Med 2002; 19(4):265-273.
(27) Welch G. Diabetes Coping Measure. In: Bradley C, editor. Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in

Diabetes Research and Practice. Londen: Harwood Academic Publishers, 1994: 400.
(28) Halfens R. Locus of Control:De beheersingsorientatie in relatie tot ziekte- en gezondheidsgedrag. Limburg University, 1985.
(29) Anderson RM, Funnell MM, Carlson A, Saleh-Statin N, Cradock S, Skinner TC. Facilitating Self-care Through Empowerment. In: Snoek FJ, Skinner TC, editors. Psychology in Diabetes Care. Chichester: John Wiley & Sons, LTD, 2000: 69-98.
(30) Anderson RM, Funnell MM. Compliance and adherence are dysfunctional concepts in diabetes care. Diabetes Educ 2000; 26(4):597-604.
(31) Campbell DT, Kenny DA. A primer on Regression Artifacts. 1 ed. New York: The Guilford Press, 1999.
(32) Muhlhauser I, Berger M. Patient education - evaluation of a complex intervention. Diabetologia 2002; 45(12):1723-1733.
(33) Funnell MM, Anderson RM, Arnold MS, Barr PA, Donnelly M, Johnson PD et al. Empowerment: an idea whose time has come in diabetes education. Diabetes Educ 1991; 17(1):37-41.
(34) Anderson RM, Funnell MM, Barr PA, Dedrick RF, Davis WK. Learning to empower patients. Results of professional education program for diabetes educators [published erratum appears in Diabetes Care 1991 Oct;14(10):933]. Diabetes Care 1991; 14(7):584-590.
(35) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1995; 18:943-949.
(36) Glasgow RE, Anderson RM. In diabetes care, moving from compliance to adherence is not enough. Something entirely different is needed [letter]. Diabetes Care 1999; 22(12):2090-2092.
(37) Howorka K, Pumprla J, Wagner-Nosiska D, Grillmayr H, Schlusche C, Schabmann A. Empowering diabetes out-patients with structured education: short-term and long-term effects of functional insulin treatment on perceived control over diabetes. J Psychosom Res 2000; 48(1):37-44.
(38) Anderson RM, Funnell MM, Fitzgerald JT, Marrero DG. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. Diabetes Care 2000; 23(6):739-743.
(39) van der Ven NC, Weinger K, Yi J, Pouwer F, Ader H, Van Der Ploeg HM et al. The confidence in diabetes self-care scale: psychometric properties of a new measure of diabetes-specific self-efficacy in Dutch and US patients with type 1 diabetes. Diabetes Care 2003; 26(3):713-718.
(40) Glasgow RE, Osteen VL. Evaluating diabetes education. Are we measuring the most important outcomes? Diabetes Care 1992; 15(10):1423-1432.

(41) Hunt LM, Pugh J, Valenzuela M. How patients adapt diabetes self-care recommendations in everyday life. Journal of Family Practice 1998; 46(3):207-215.
(42) Glasgow RE, Fisher EB, Anderson BJ, LaGreca A, Marrero D, Johnson SB et al. Behavioral science in diabetes. Contributions and opportunities. Diabetes Care 1999; 22(5):832-843.
(43) Hanestad BR, Albrektsen G. Quality of life, perceived difficulties in adherence to a diabetes regimen, and blood glucose control. Diabet Med 1991; 8(8):759-764.
(44) Johnson SB. Methodological issues in diabetes research. Measuring adherence. Diabetes Care 1992; 15(11):1658-1667.
(45) Toobert DJ, Glasgow RE. Assessing Diabetes Self-Management: The Summary of Diabetes Self-Care Activities Questionnaire. In: Bradley C, editor. Handbook of Psychology and Diabetes. Amsterdam: Harwood Academic Publishers, 1994: 351-375.
(46) Peyrot M, Rubin RR. Modeling the effect of diabetes education on glycemic control. Diabetes Educ 1994; 20(2):143-148.
(47) Hanson CL, De Guire MJ, Schinkel AM, Kolterman OG, Goodman JP, Buckingham BA. Self-care behaviors in insulin-dependent diabetes: evaluative tools and their associations with glycemic control. J Pediatr Psychol 1996; 21(4):467-482.
(48) Glasgow RE, Eakin EG, Toobert DJ. How generalizable are the results of diabetes self-management research? The impact of participation and attrition. Diabetes Educ 1996; 22(6):573-2,584.
(49) Toobert DJ, Strycker LA, Glasgow RE, Bagdade JD. If you build it, will they come?. Reach and Adoption associated with a comprehensive lifestyle management program for women with type 2 diabetes. Patient Educ Couns 2002; 48(2):99-105.
(50) Muhlhauser I, Berger M. Evidence-based patient information in diabetes. Diabet Med 2000; 17(12):823-829.
(51) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1997; 18:943-949.
(52) Day JL. Why should patients do what we ask them to do? Patient Educ Couns 1995; 26(1-3):113-118.
(53) Coates VE, Boore JR. Knowledge and diabetes self-management. Patient Educ Couns 1996; 29(1):99-108.
(54) Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. Diabetes Care 1997; 18:943-949.
(55) Colagiuri R, Colagiuri S, Naidu V. Can patients set their own educational priorities? Diabetes Res Clin Pract 1995; 30(2):131-136.

(56) Glasgow RE, McKay HG, Piette JD, Reynolds KD. The RE-AIM framework for evaluating interventions: what can it tell us about approaches to chronic illness management? Patient Educ Couns 2001; 44(2):119-127.
(57) Glasgow RE, Eakin EG. Medical Office-based Interventions. In: Snoek FJ, Skinner TC, editors. Psychology in Diabetes Care. Chichester: John Wiley & Sons, 2000: 141-168.
(58) Welch GW, Jacobson AM, Polonsky WH. The Problem Areas in Diabetes Scale. An evaluation of its clinical utility. Diabetes Care 1997; 20(5):760-766.
(59) Fain JA, Nettles A, Funnell MM, Charron D. Diabetes patient education research: an integrative literature review. Diabetes Educ 1999; 25(6 Suppl):7-15.
(60) Renders CM, Valk GD, Griffin S, Wagner EH, Eijk JT, Assendelft WJ. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. Cochrane Database Syst Rev 2001; 1:CD001481.
(61) Rubin RR, Peyrot M. Psychosocial problems and interventions in diabetes. A review of the literature. Diabetes Care 1992; 15(11):1640-1657.
(62) Laupacis A, Sackett DL, Roberts RS. An assessment of clinically useful measures of the consequences of treatment. N Engl J Med 1988; 318(26):1728-1733.
(63) Brown SA. Meta-analysis of diabetes patient education research: variations in intervention effects across studies. Res Nurs Health 1992; 15(6):409-419.
(64) Keers JC, Links TP, Bouma J, Gans ROB, Maaten JCt, Wolffenbuttel BHR et al. Do Diabetologists Recognise Self-Management Problems in their Patients? Diabetes Res Clin Pract. In press.
(65) Sadur CN, Moline N, Costa M, Michalik D, Mendlowitz D, Roller S et al. Diabetes management in a health maintenance organization. Efficacy of care management using cluster visits. Diabetes Care 1999; 22(12):2011-2017.
(66) Testa MA, Simonson DC. Health economic benefits and quality of life during improved glycemic control in patients with type 2 diabetes mellitus: a randomized, controlled, double-blind trial. JAMA 1998; 280(17):1490-1496.
(67) Diabetes Control and Complications Trial Research Group (DCCT). Lifetime benefits and costs of intensive therapy as practiced in the diabetes control and complications trial. The Diabetes Control and Complications Trial Research Group [see comments] [published erratum appears in JAMA 1997 Jul 2;278(1):25]. JAMA 1996; 276(17):1409-1415.
(68) Rubin RR, Peyrot M. Quality of life and diabetes. Diabetes Metab Res Rev 1999; 15:205-218.

(69) UKPDS. Quality of life in type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control (UKPDS 37). U.K. Prospective Diabetes Study Group. Diabetes Care 2000; 22:1125-1136.
(70) Cook TD, Campbell DT. Quasi-Experimentation. Design and Analysis Issues for Field Settings. Boston: Houghton Mifflin Company, 1979.
(71) Bradley C, Gamsu DS. Guidelines for encouraging psychological well-being: report of a Working Group of the World Health Organization Regional Office for Europe and International Diabetes Federation European Region St Vincent Declaration Action Programme for Diabetes. Diabet Med 1994; 11(5):510-516.
(72) Goddijn PP, Bilo HJ, Feskens EJ, Groeniert KH, van-der-Zee KI, Meyboom-de JB. Longitudinal study on glycaemic control and quality of life in patients with Type 2 diabetes mellitus referred for intensified control. Diabet Med 1999; 16(1):23-30.
(73) Henon PR. Human embryonic or adult stem cells: an overview on ethics and perspectives for tissue engineering. Adv Exp Med Biol 2003; 534:27-45.
(74) Chaudhari M, Cornelius JG, Schatz D, Peck AB, Ramiya VK. Pancreatic stem cells: a therapeutic agent that may offer the best approach for curing type 1 diabetes. Pediatr Diabetes 2001; 2(4):195-202.
(75) Logdberg L, Sgan SL, Larsen CP, Hillyer CD. Islet transplantation, stem cells, and transfusion medicine. Transfus Med Rev 2003; 17(2):95-109.
(76) International Diabetes Federation. Diabetes e-Atlas. http://www.idf.org/e-atlas . 2003. Ref Type: Electronic Citation
(77) WHO. Defenition, Diagnosis and Classification of Diabetes and its Complications. Geneva: 1999.

Summary

Summary

Diabetes is a common chronic disease with a growing prevalence world-wide. In the Netherlands, the total number of known people with diabetes is about 500.000. Type 1 and type 2 are the most common forms of diabetes. Type 1 diabetes is usually contracted at a fairly early age and 10-15% of all diabetic patients have type 1 diabetes. In this type of diabetes, the beta cells of the islets of Langerhans in the pancreas are destroyed, resulting in a stop in the production of insulin. Treatment of type 1 diabetes consists of insulin substitution therapy. Type 2 diabetes is usually acquired later in life and about 85% to 90% of all diabetic patients have this type of diabetes. The number of people with type 2 diabetes is expected to continue to rise. In type 2 diabetes, there is a relative deficiency in insulin because the body tissues are to a certain extent resistant to insulin and the pancreas cannot compensate for the increased demand for insulin. Treatment of type 2 diabetes consists of a diet adapted to needs and medication which increases insulin production and/or heightens insulin sensitivity. In time, treatment with insulin is necessary for many type 2 diabetic patients. The primary treatment goal in both type 1 and type 2 diabetes is to normalise blood glucose levels. Prolonged poor glycaemic control increases patients' risk of developing complications such as neuropathy, retinopathy or nephropathy. Other risk factors for the development of complications are high blood pressure, disturbed blood lipids and obesity.

The medical developments of the last three decades have changed diabetes treatment from a rigid regimen into a more dynamic approach. This means that diabetes has more and more become a disease whose treatment relies on self-management. Diabetes education is the obvious and generally acknowledged way to provide patients with the knowledge and skills that are needed for adequate self-care. In spite of diabetes education and technical developments for self-regulation only a limited number of people with diabetes have good diabetes control. Diabetes requires lifelong active daily efforts from patients and this health behaviour eventually can determine their well-being and health to a great extent. Health behaviour, however, depends on many factors which can impede adaptation to a life with diabetes and which can constitute an obstacle to optimal self-management. For this reason, diabetes is considered one of the psychologically most burdensome diseases.

Roughly, two approaches with respect to diabetes education can be distinguished: the compliance-based approach and the patient empowerment approach. The former refers to more traditional, biomedically oriented education which expects patients to follow the prescriptions of a health care professional. Because the treatment of diabetes has such a large behavioural component, diabetes education requires a more biopsychosocial empowerment-based approach. The rehabilitation programme MIEP (Multidisciplinary Intensive Education Programme) described in this thesis is

an example of an intervention that is based explicitly on the empowerment approach.

In the 1990s it became increasingly clear that some diabetic patients had prolonged self-management difficulties maintaining adequate diabetes self-management in spite of intensive outpatient care and optimised medical treatment. These problems manifested themselves in insufficient glycaemic regulation as well as in diabetes-related distress. There was a need for additional diabetes care for a specific subgroup of patients with self-management difficulties, who had not yet developed major complications but who did run a high risk of doing so. An intensive outpatient intervention was thought to meet the care needs of this group of patients. For this reason, a 12-day outpatient programme for rehabilitation was developed, involving the departments of Diabetes Rehabilitation, Endocrinology, Internal Medicine and the Northern Centre for Healthcare Research. MIEP consists of a core module of 10 weekly sessions and has follow-up sessions at 6 and 12 weeks. Elements that have proven useful in earlier intervention studies have been fitted into the rehabilitation programme wherever possible.

Four studies were performed as part of the project described in this thesis. First a pilot study was performed among 51 participants of MIEP, which focussed on 3-months effects of MIEP on HbA1c, health-related quality of life and knowledge with the aim to test the programme. The next study (MIEP-1) was a longitudinal study with measures at baseline (T0), 3 months (T1) and 1 year (T2) after the intervention. Ninety patients participated in this study focussing on the effects and mechanisms of effect of MIEP. The MIEP-2 study was comparable to MIEP-1, but measures for diabetes-related distress and costs were added and after the core module of MIEP patients were randomised to telephonic booster sessions. Seventy-six patients participated in MIEP-2. MIEP-3 concerns a cross-sectional study among 231 consecutive, non-referred outpatients. The diabetologists of these patients stated if they perceived them eligible for MIEP.

The thesis addresses three main research questions.:

1. **What are the effects of MIEP?**
2. **For whom is MIEP effective?**
3. **Which factors contribute to the effects of MIEP?**

Chapter 2 describes the development of the empowerment-based Multidisciplinary Intensive Education Programme (MIEP) and it presents the findings of a pilot study among 51 participants of MIEP. Patients' glycated haemoglobin (HbA1c), health-related quality of life (HR-QoL), health locus of control, psychosocial distress and diabetes knowledge were obtained at baseline and three months follow-up. HbA1c and diabetes knowledge improved significantly, patients rated themselves healthier and were more internal and less powerful others oriented. Baseline scores of the outcomes

explained effects in HbA1c and health-related quality of life. Health locus of control contributed significantly to the effects in health-related quality of life. It was concluded that MIEP benefits patients with prolonged self-management difficulties and that the form of care delivered in MIEP seems to complement regular outpatient diabetes care.

In *Chapter 3* the effects of MIEP at three months follow-up are described. In 89 participants, HbA1c, health-related quality of life and indicators of empowerment were measured before MIEP and at 12 weeks follow-up. The participants were compared with 231 non-referred, average outpatients who were measured once. Since participants of MIEP pursue different treatment goals, subgroups of patients with poor and satisfactory HbA1c and high and low levels of mental health were distinguished. Overall, participants improved their HbA1c, their mental health and became more satisfied with treatment and more empowered according to measures for health locus of control and diabetes-related coping. Post-MIEP, participants and outpatients hardly differed in any outcome. Subgroup-analyses revealed that especially patients with poor HbA1c at T0 improved in this. At T0, participants with poor mental health also had worse HR-QoL in other domains and were less empowered compared to the satisfactory mental health group. Patients with poor mental health improved in most of these aspects and differences in subgroups became smaller. In conclusion, MIEP is effective for patients with different treatment goals, though inclusion criteria need further elaboration.

Chapter 4 reports the one-year follow-up effects of MIEP and the role of indicators of empowerment in the effects of MIEP. HbA1c, HR-QoL and indicators of empowerment (health locus of control and coping) were measured at T0, T1 and T2 follow-up and cross-sectionally in 231 non-referred consecutive outpatients. Mean HbA1c improved at T2, although initial improvement found at T1 was partially lost. Participants improved in most HR-QoL domains, without any relapse at T2. At T2, participants no longer differed from the average outpatients in any outcome. Initially, HbA1c in men and women improved about equally, but at T2 women consolidated improvement, whereas men relapsed. After MIEP, patients became more empowered, explaining additional variance in HR-QoL improvements. This chapter concludes that the aim of MIEP to empower patients, rather than trying to solve problems for them, seems an effective approach.

Chapter 5 compares the costs and benefits of MIEP and provides inclusion criteria for optimal outcomes of the intervention. Sixty-one participants of MIEP were measured at T0 and at T2. Data were obtained concerning glycaemic control (HbA1c), diabetes-related distress (PAID) and costs. Changes over time were analysed and means at T0 and T2 were compared to a reference group of non-referred consecutive outpatients. The number

needed to treat (NNT) (i.e. the number of patients to be treated in order to achieve one successful case) was calculated for different baseline values of HbA1c and PAID, in order to determine optimal inclusion criteria. The diabetes-related costs decreased significantly, and patients improved significantly in HbA1c and diabetes-related distress following MIEP. The levels of HbA1c and distress of the participants reached those of the reference group. The T2 costs remained higher than those of the reference group, but the reduction in costs outweighed the intervention costs. Including patients with baseline HbA1c ≥ 8.0%, PAID scores ≥ 40, or both, would improve the NNT to achieve clinically relevant improvements from 1.80 to 1.48. Seventy-six percent of the patients in this study met these inclusion criteria. Chapter 5 concludes that even using the current inclusion criteria, MIEP is cost-effective and facilitates improvement in patients. However, stricter inclusion criteria with respect to HbA1c and PAID scores may further improve the programme's efficacy.

Chapter 6 describes to what extent diabetologists recognise patients' needs for additional diabetes care due to poor glycaemic control and diabetes-related psychosocial problems. A hundred-and-fourteen participants of MIEP were compared with 201 as yet non-referred outpatients, of whom 54 were considered eligible for the intervention by their diabetologists; thus 147 outpatients were considered non-eligible. Eligible patients had worse glycaemic control but did not distinguish themselves by other parameters. Glycaemic control was the main trigger for diabetologists to consider MIEP. Significantly, 22 (15%) of the 147 non-eligible patients clearly had diabetes distress and could potentially benefit from the intervention. This finding discussed in this chapter suggests that the detection of diabetes related psychosocial problems in outpatients could be improved. Integrated monitoring of diabetes-related psychosocial distress may improve recognition of care needs in outpatient diabetes care.

Chapter 7 reports the findings of a study on the use of telephonic reminders after MIEP. For this purpose, patients were asked to participate in four three-monthly telephonic interviews structured on participants' personal diabetes-related goals. Patients were randomised to receiving calls (N=22) or not (N=27). Twenty-six patients refused to participate. These three groups were compared. Two-hundred-and-thirty-one non-referred outpatients served as a reference group. Glycaemic control, diabetes-related distress and indicators of empowerment were measured. In general, patients improved in HbA1c, diabetes-related distress and became more empowered after MIEP, and reached the levels of the average outpatients. No additional effect of the telephonic reminders was found upon the already good results of MIEP. The patients who refused to take part in the booster sessions only had lower diabetes-related distress throughout the study. Chapter 7 discusses the

possibilities for a more effective use of booster sessions for a subgroup of patients.

Chapter 8 describes that the beneficial effects of self-management education for patients with diabetes can be undermined if the spousal context is incongruous with the empowerment approach, that is if the spouse is perceived to be overprotective. Sixty-nine participants of MIEP with a spouse were assessed on spousal overprotection and on HbA1c, diabetes-related distress and internal health locus of control at baseline and at three months follow-up. Regression analyses showed that the increase in internal locus of control and the decrease in HbA1c were significantly lower in female patients who perceived their spouse to be overprotective when they entered MIEP. Moreover, regardless of gender, patients who perceived their spouses to be overprotective at baseline showed a significantly smaller decrease in diabetes-related distress than patients who did not perceive their spouses to be overprotective. These findings suggest that not only the patient, but also the spouse should be targeted in education programmes to optimise their effectiveness, especially for (female) patients with an overprotective spouse.

Chapter 9 discusses the main findings of this thesis according to the three main research questions of this thesis: 1) What are the effects of MIEP?; 2) For whom is MIEP effective?; 3) Which determinants contribute to the effects of MIEP?

(1) The effects of MIEP have been studied in several domains, i.e. glycaemic control, HR-QoL, diabetes-related distress, indicators of empowerment and cost parameters. In sum, lasting, statistically significant and clinically relevant positive changes were found in glycaemic control, psychosocial variables and costs. The participants' mean HbA1c improved without the number of hypoglycaemia increasing. Moreover, health-related quality of life improved in several domains and diabetes-related distress decreased. Furthermore, the mean scores in health locus of control and coping scales indicated the participants of MIEP to have become more empowered. One year after MIEP, almost no differences were found between participants of MIEP and the consecutive outpatients. These results were particularly satisfying concerning the target group of MIEP having prolonged self-management difficulties.

(2) In sum, MIEP is especially effective for patients with HbA1c ≥ 8.0% (poor glycaemic control) and / or PAID scores ≥ 40 (high distress). Interestingly, women seem better able to retain improved HbA1c after MIEP.

(3) The determinants contributing to the effects of MIEP can be defined as the processes in patients that facilitate improvements and they can be defined as the characteristics of the intervention itself. The results suggest that in the short-term, patients' HbA1c and HR-QoL improved fairly independently of changes in indicators of empowerment. In order to maintain

or to further improve HR-QoL, it is important to consolidate improvements in coping with diabetes and health locus of control. Changes in HbA1c were weakly related to changes in diabetes related coping and health locus of control. The fact that MIEP combines many elements that contribute to the efficacy of a diabetes self-management intervention makes it difficult to determine how the separate elements have contributed to the effects. Moreover, it is difficult to select the best predicting determinants of diabetes self-management, being very complex behaviour.

In addition to a review of the findings in light of the three main research questions, methodological, theoretical and practical considerations are made. This chapter ends with recommendations for practical implications and for future research.

Samenvatting

Samenvatting

Diabetes is een veelvoorkomende chronische ziekte met wereldwijd een groeiende prevalentie. Het aantal bekende patiënten met diabetes is ongeveer 500.000. Type 1 en type 2 diabetes komen het meest voor en dit proefschrift heeft betrekking op deze beide vormen. Type 1 diabetes ontstaat meestal op vrij jonge leeftijd en omvat 10 tot 15% van de patiënten met diabetes. Bij type 1 zijn de Bëta cellen van de eilandjes van Langerhans in de pancreas (alvleesklier) vernietigd waardoor er geen insuline geproduceerd wordt. De behandeling van type 1 diabetes bestaat uit insuline substitutie therapie.

Type 2 diabetes ontstaat meestal op latere leeftijd en omvat ongeveer 85 tot 90% van de patiënten met diabetes. Het aantal patiënten met type 2 zal naar verwachting blijven stijgen. Bij type 2 diabetes bestaat er een relatief tekort aan insuline doordat de lichaamsweefsels in zekere mate resistent zijn tegen insuline en de pancreas de toegenomen behoefte aan insuline niet kan compenseren. De behandeling van type 2 diabetes bestaat uit een gezond dieet afgestemd op de behoeften van de patiënt en uit medicijnen die de insulineproductie verhogen en/of de insulinegevoeligheid vergroten. Na verloop van tijd wordt voor een aanzienlijk deel van de type 2 diabetespatiënten behandeling met insuline noodzakelijk. Zowel bij type 1 als type 2 diabetes is het primaire behandeldoel het normaliseren van de bloedglucosespiegel. Een langdurig slechte glycemische controle (bloedsuikerregulatie) verhoogt de kans op het ontwikkelen van complicaties zoals neuropathie, retinopathie en nephropathie (schade aan respectievelijk zenuwen, netvlies en nieren). Ook andere factoren zoals een verhoogde bloeddruk, verstoringen in de bloedvetten en overgewicht dragen bij aan de ontwikkeling van complicaties.

Door de medische ontwikkelingen in de afgelopen drie decennia is de behandeling van diabetes veranderd van een star behandelregime in een meer dynamische benadering. Diabetes is zo steeds meer een aandoening geworden waarbij zelfmanagement centraal staat in de behandeling. Diabeteseducatie is de aangewezen en algemeen erkende manier om patiënten de kennis en vaardigheden bij te brengen die nodig zijn voor een adequate zelfzorg. Ondanks diabeteseducatie en recente technische ontwikkelingen op het gebied van zelfregulatie blijkt slechts een beperkt deel van de mensen met diabetes een goede glycemische regulatie te hebben. Diabetes vereist een levenslange, dagelijkse actieve bijdrage van de patiënt zelf en dit gezondheidsgedrag is uiteindelijk zeer bepalend voor het welzijn en de gezondheid van de patiënt. Gezondheidsgedrag is echter afhankelijk van vele factoren die de adaptatie aan een leven met diabetes kunnen bemoeilijken en een barrière kunnen vormen voor optimaal zelfmanagement. Diabetes wordt dan ook beschouwd als één van de psychisch meest belastende aandoeningen.

Grofweg kunnen er twee benaderingen worden onderscheiden met betrekking tot diabeteseducatie: de één is gebaseerd op therapietrouw (compliance) en de andere op 'empowerment'. Onder 'compliance' wordt de meer traditionele biomedisch gerichte educatie verstaan, waarin de patiënt geacht wordt de voorschriften van behandelaars op te volgen. Aangezien gedrag een zeer belangrijke rol speelt in de behandeling vraagt diabeteseducatie een meer biopsychosociale, empowerment benadering. De empowerment gaat er vanuit dat de patiënt met diabetes uiteindelijk zelf het succes van de behandeling bepaalt en dat de behandeling moet worden afgestemd op de persoonlijke situatie, behoeften en wensen van de patiënt. Het revalidatieprogramma MIEP (Multidisciplinair Intensief Educatie Programma) is een voorbeeld van een interventie die expliciet uitgaat van de empowerment benadering.

Halverwege de jaren '90 bleek in toenemende mate dat een deel van de diabetespatiënten ondanks intensieve poliklinische zorg en het optimaliseren van de medische behandeling langdurig problemen ondervond bij het handhaven van adequaat diabetes zelfmanagement. Deze problemen uitten zich zowel in onvoldoende glycemische regulatie alsook in diabetesgerelateerde 'distress' (psychosociale problematiek). Er bestond behoefte aan aanvullende diabeteszorg voor een specifieke groep van diabetespatiënten met zelfmanagement problemen die echter nog geen ernstige complicaties had ontwikkeld, maar wel een verhoogd risico liep. Om deze reden is er in Groningen een dagbehandeling van twaalf dagen ontwikkeld gericht op revalidatie, waarbij de afdelingen Diabetesrevalidatie (Beatrixoord), Endocrinologie, Interne Geneeskunde en het Noordelijk Centrum voor Gezondheidsvraagstukken waren betrokken. Het programma bestaat uit tien dagen educatie in tien weken en vervolgdagen na zes en twaalf weken. In dit programma zijn zoveel mogelijk werkzaam gebleken elementen van eerdere interventiestudies ingepast in een praktisch werkbare dagbehandeling.

In het kader van het project zijn vier deelstudies uitgevoerd. Er is gestart met een pilotstudie onder 51 deelnemers aan MIEP die zich richtte op de effecten met betrekking tot HbA1c, gezondheidsgerelateerde kwaliteit van leven en kennis drie maanden na MIEP, met als doel het programma te testen. De volgende deelstudie (MIEP-1) was een longitudinale studie met meetmomenten bij aanvang van revalidatie (T0) en drie (T1) en twaalf (T2) maanden na afloop. Er namen negentig revalidanten deel aan deze studie naar de effecten en werkingsmechanismen van MIEP. De hierop volgende studie (MIEP-2) was vergelijkbaar met MIEP-1 en dezelfde meetmomenten (T0, T1 en T2) werden gebruikt. Het verschil was dat er meetinstrumenten voor diabetes gerelateerde distress en kosten waren toegevoegd en na T1 werden patiënten gerandomiseerd naar wel of geen telefonische vervolgcontacten. Er namen 76 revalidanten deel aan deze studie. MIEP-3 is een cross-sectionele (eenmalige meting) studie onder 231 opeenvolgende, niet

verwezen patiënten die behandeld werden op de polikliniek. Tevens werd bij elke patiënt in deze referentiegroep aan de behandelend internist/endocrinoloog gevraagd of hij/zij MIEP nodig achtte voor de betreffende patiënt.

In dit proefschrift wordt aandacht besteed aan de volgende drie hoofdonderzoeksvragen:

1. **Wat zijn de effecten van MIEP?**
2. **Voor wie is MIEP effectief?**
3. **Welke factoren dragen bij aan de effectiviteit van MIEP?**

In hoofdstuk 2 wordt de ontwikkeling beschreven van MIEP. Dit hoofdstuk behandelt tevens de uitkomsten van de pilotstudie onder 51 revalidanten. Bij de patiënten werd geglycoliseerd hemoglobine (HbA1c), gezondheidsgerelateerde kwaliteit van leven, kennis over diabetes en 'health locus of control' gemeten voor het begin van revalidatie en drie maanden na afloop. HbA1c is een standaard bepaling voor de gemiddelde bloedsuikerregulatie in de voorgaande zes tot acht weken. Een HbA1c onder de 7% betekent een goede regulatie, en boven de 8% wordt beschouwd als een slechte regulatie. Onder 'health locus of control' wordt de mate verstaan waarin mensen hun gezondheid als afhankelijk beschouwen van hun eigen inspanningen (intern georiënteerd), toeval (kans georiënteerd) of de invloed van anderen (georiënteerd op invloedrijke anderen).

HbA1c en kennis over diabetes verbeterden significant, revalidanten vonden zichzelf gezonder en kregen een meer interne oriëntatie en hadden minder het idee dat invloedrijke anderen bepalend waren voor hun gezondheid. De effecten op HbA1c en gezondheidsgerelateerde kwaliteit van leven konden worden verklaard op basis van de uitgangswaarden: revalidanten met de slechtste uitgangswaarden verbeterden het meeste. Health locus of control droeg significant bij aan het verklaren van de effecten in de gezondheidsgerelateerde kwaliteit van leven. Er werd geconcludeerd dat patiënten met langdurige zelfmanagement problemen baat hebben bij MIEP en dat deze vorm van diabeteszorg een waardevolle aanvulling lijkt op reguliere poliklinische diabeteszorg.

De effecten van MIEP drie maanden na revalidatie worden beschreven in hoofdstuk 3. Hiertoe werden bij 89 patiënten HbA1c, gezondheidsgerelateerde kwaliteit van leven (KvL) en indicatoren van empowerment gemeten voordat deze patiënten startten met MIEP (T0) en drie maanden na afloop (T1). De revalidanten werden vergeleken met 231 niet-verwezen, doorsnee poliklinische patiënten. Aangezien revalidanten verschillende behandeldoelen hebben, werden er subgroepen met een slechte en redelijk tot goede regulatie onderscheiden en met een goede en slechte mentale gezondheid. In het algemeen verbeterde het HbA1c en de mentale

gezondheid en voelden revalidanten zich meer tevreden met hun behandeling en ook nam de empowerment toe gemeten met vragenlijsten over 'diabetes coping' en 'health locus of control'. De revalidanten en poliklinische patiënten verschilden niet meer wat betreft HbA1c en mentale gezondheid na afloop van de revalidatie. Analyse op subgroep niveau liet zien dat met name het HbA1c van de patiënten met de hoogste aanvangswaarde van HbA1c verbeterde. Op T0 hadden de revalidanten met een slechte mentale gezondheid tevens een lagere score op andere domeinen van KvL en waren ze minder 'empowered' in vergelijking met de groep met een beter mentaal functioneren. De groep met een lage mentale gezondheid verbeterde voor wat betreft de meeste van deze aspecten en de verschillen tussen de subgroepen werden kleiner. In dit hoofdstuk wordt geconcludeerd dat MIEP effectief is voor patiënten met diverse behandeldoelen en dat de inclusiecriteria voor MIEP verdere uitwerking behoeven.

In hoofdstuk 4 worden de effecten één jaar na MIEP beschreven en is de rol onderzocht van indicatoren van empowerment op de uitkomsten van deelnemers aan revalidatie. HbA1c, KvL en indicatoren van empowerment werden gemeten bij de revalidanten van de MIEP-1 studie en een deel van de revalidanten van de MIEP-2 studie op T0, T1 en T2 en cross-sectioneel bij 231 niet-verwezen opeenvolgende patiënten van de polikliniek. Het gemiddelde HbA1c was verbeterd op T2, hoewel de verbetering op korte termijn (T1) gedeeltelijk verloren ging. Bovendien verbeterden de revalidanten op de meeste domeinen van gezondheidsgerelateerde kwaliteit van leven zonder dat er sprake was van een terugval op T2. Op T2 werden er geen verschillen meer gevonden tussen revalidanten en poliklinische patiënten in alle uitkomstmaten. Aanvankelijk verbeterde het HbA1c ongeveer evenveel bij mannen als bij vrouwen, maar vrouwelijke revalidanten wisten deze verbetering vast te houden tot een jaar na revalidatie terwijl mannelijke revalidanten een terugval lieten zien. De revalidanten werden meer empowered na afloop van MIEP waarmee de verbeteringen in gezondheidsgerelateerde kwaliteit van leven te verklaren waren: de verklaarde variantie nam toe. Dit hoofdstuk sluit af met de conclusie dat het doel van MIEP om patiënten in staat te stellen zelf problemen op te lossen in plaats van problemen voor hen proberen op te lossen een effectieve benadering lijkt.

In hoofdstuk 5 worden de kosten en baten van MIEP vergeleken en worden de inclusie criteria bepaald die tot optimale uitkomsten van de interventie leiden. Eenenzestig revalidanten werden gemeten op T0 en T2 wat betreft glycemische controle (HbA1c), diabetes gerelateerde distress (PAID) en diabetes gerelateerde kosten. De veranderingen in de tijd werden geanalyseerd en de gemiddelden op T0 en T2 werden vergeleken met de referentiegroep van niet verwezen doorsnee poliklinische diabetespatiënten.

Het 'number needed to treat' (NNT) (d.w.z. het aantal patiënten dat behandeld moet worden om één succesvol behandelde patiënt te verkrijgen) werd voor verschillende aanvangswaarden van het HbA1c en de PAID vragenlijst berekend om de optimale inclusiecriteria te bepalen. De diabetesgerelateerde kosten namen significant af na MIEP en de revalidanten verbeterden significant op HbA1c en diabetesgerelateerde distress. Deze waarden bereikten die van de referentiegroep. De kosten op T2 bleven weliswaar hoger dan de kosten die de patiënten in de referentiegroep genereerden, maar de reductie in kosten overtrof de kosten van de interventie. Het NNT om klinisch relevante verbeteringen te bereiken kan verbeterd worden met het includeren van patiënten op basis van HbA1c ≥ 8,0%, PAID scores ≥ 40 of beide. Van de patiënten in deze studie voldeed 76% aan deze inclusiecriteria. In hoofdstuk 5 wordt geconcludeerd dat MIEP reeds met de huidige selectie kosteneffectief is en tot goede patiëntgebonden uitkomsten leidt. Een striktere inclusie op basis van zowel HbA1c als PAID scores kan de effectiviteit van MIEP nog verder verbeteren.

In hoofdstuk 6 wordt besproken in welke mate internisten / endocrinologen de behoefte voor aanvullende zorg herkennen bij hun patiënten, vanwege een slechte glycemische controle en vanwege psychosociale problematiek. Er werden 114 revalidanten vergeleken met 201 nog niet verwezen poliklinische patiënten. Van de 201 niet verwezen patiënten werden 54 door hun behandelend arts geschikt geacht voor revalidatie; 147 poliklinische patiënten werden dus niet geschikt geacht. De 54 poliklinische patiënten hadden wel een slechtere glycemische regulatie, maar onderscheidden zichzelf niet op andere parameters. Voor behandelend artsen was de glycemische controle de belangrijkste reden om MIEP te overwegen. Het is vermeldenswaardig dat 22 (15%) van de 147 patiënten waarvoor MIEP niet werd overwogen duidelijke diabetesgerelateerde distress rapporteerden. Deze potentiële revalidanten werden echter niet als zodanig herkend door hun behandelaar. De resultaten van hoofdstuk 6 wijzen erop dat de zorgbehoeften van patiënten met psychosociale problematiek beter herkend moeten worden. Het structureel en geïntegreerd in de poliklinische zorg monitoren van psychosociale distress kan helpen om dit te bereiken.

In hoofdstuk 7 worden de bevindingen van een studie naar het effect van telefonische herinneringen na MIEP behandeld. Deze herinneringen hadden als doel revalidanten te helpen de effecten van de dagbehandeling vast te houden. Voor deze studie werden patiënten gevraagd deel te nemen aan vier telefonische interviews die gestructureerd waren op basis van de persoonlijke doelen van de revalidanten. De deelnemers werden eens per drie maanden benaderd. De patiënten werden willekeurig toegewezen (gerandomiseerd) aan een groep die de telefonische interviews (22 revalidanten) ontving of een groep die deze niet ontving (27 revalidanten). Daarnaast waren er 26

patiënten doe niet wilden deelnemen. De eerder genoemde 231 poliklinische patiënten dienden als referentiegroep. Zoals hiervoor vermeld verbeterden de revalidanten over het algemeen op HbA1c, diabetesgerelateerde distress en ze werden meer empowered na MIEP, waarbij ze het niveau van de referentiegroep bereikten. Er werd geen additioneel effect gevonden als gevolg van de telefonische interviews bovenop de reeds goede resultaten van MIEP. Gedurende de hele studie periode rapporteerden de patiënten die niet wilden deelnemen aan de telefonische interviews minder diabetesgerelateerde distress, zonder zich op andere parameters te onderscheiden. In de discussie van hoofdstuk 7 worden de mogelijkheden besproken voor het effectiever gebruik van herinneringen voor een subgroep van revalidanten.

In hoofdstuk 8 wordt beschreven of de gunstige effecten van zelfmanagement educatie voor mensen met diabetes kunnen worden ondermijnd wanneer de context van de partnerrelatie niet strookt met de empowerment benadering. Dit is het geval wanneer de partner als overbeschermend wordt ervaren door de patiënt. Bij 69 revalidanten met een partner werd gemeten in hoeverre het gedrag van de partner als overbeschermend werd ervaren. Ook het HbA1c, de diabetesgerelateerde distress en de interne health locus of control werd gemeten op T0 en T1. Regressie analyse toonde aan dat bij vrouwen die hun partner overbeschermend vonden de toename in interne locus of control en de afname in HbA1c significant kleiner was in vergelijking met vrouwen waarbij dit niet het geval was. Bovendien rapporteerden revalidanten die hun partner overbeschermend vonden een kleinere afname in diabetesgerelateerde distress dan de patiënten die hun partners niet overbeschermend vonden, ongeacht het geslacht van de revalidant. Revalidanten die hun partner als overbeschermend ervaren hebben dus gemiddeld minder baat bij MIEP dan revalidanten die hun partner niet overbeschermend vinden. Om diabetes educatie programma's verder te optimaliseren zouden ze niet alleen gericht moeten zijn op de patiënt, maar ook op diens partner om zo de effectiviteit van deze programma's te vergroten. Dit geldt vooral voor (vrouwelijke) patiënten die het gedrag van hun partner als overbeschermend ervaren.

Aan de hand van de drie hoofdonderzoeksvragen worden in hoofdstuk 9 de belangrijkste bevindingen van dit proefschrift besproken. Deze onderzoeksvragen waren: (1) Wat zijn de effecten van MIEP?; (2) Voor wie is MIEP effectief?; (3) Welke factoren dragen bij aan de effectiviteit van MIEP?

(1) De effecten van MIEP op diverse domeinen zijn onderzocht, te weten glycemische regulatie, diabetesgerelateerde distress, indicatoren van empowerment en parameters voor kosten. Er werden positieve veranderingen gevonden voor glycemische regulatie, psychosociale variabelen en kosten die blijvend, statistisch significant en klinisch relevant

waren. Het gemiddeld HbA1c van de revalidanten verbeterde zonder dat het aantal hypoglycemieën toenam. Daarnaast verbeterde de gezondheidsgerelateerde kwaliteit van leven op diverse domeinen en nam de diabetesgerelateerde distress af. Ook gaven de gemiddelde waarden op diverse indicatoren aan dat revalidanten een jaar na revalidatie een hogere mate van empowerment hadden. Een jaar na afloop van MIEP werden er vrijwel geen verschillen meer gevonden tussen de revalidanten en doorsnee diabetespatiënten op de polikliniek. In het licht van de specifieke doelgroep van MIEP, bestaande uit diabetespatiënten met langdurige problemen met zelfmanagement, zijn dit zeker gunstige uitkomsten.

(2) Kort samengevat blijkt MIEP vooral effectief voor patiënten met een HbA1c van hoger of gelijk aan 8.0% (slechte regulatie) en / of een score op de PAID vragenlijst van hoger of gelijk aan 40 (hoge mate van distress). Een interessante bevinding was dat vrouwen beter in staat bleken om een verbeterde HbA1c waarde te behouden na afloop van revalidatie.

(3) De factoren die bijdragen aan de effectiviteit van MIEP kunnen op twee manieren worden gedefinieerd. Ze kunnen worden gedefinieerd als de processen bij de deelnemers zelf die invloed hebben op de resultaten van MIEP, maar ze kunnen ook gedefinieerd worden als kenmerken van de interventie op zich. De resultaten wijzen erop dat op korte termijn het HbA1c en de KvL van revalidanten tamelijk onafhankelijk van de veranderingen in de indicatoren voor empowerment verbeterden. Het behoud van verbeteringen op deze indicatoren blijkt echter wel van belang bij het consolideren of verder verbeteren op het gebied van gezondheidsgerelateerde kwaliteit van leven. De veranderingen in HbA1c waren slechts zwak gerelateerd aan de veranderingen in de indicatoren van empowerment. Het is moeilijk om aan te geven hoe de afzonderlijke onderdelen van MIEP hebben bijgedragen aan de positieve effecten, omdat er in het programma veel elementen zijn gecombineerd die de effectiviteit ervan verhogen. Bovendien is het lastig om de beste determinanten van diabetes zelfmanagement te selecteren, omdat dit zeer complex gedrag is.

Naast de beschouwing van de resultaten in het licht van de drie hoofdonderzoeksvragen komen in dit laatste hoofdstuk methodologische, theoretische en praktische overwegingen aan de orde. Hoofdstuk 9 sluit af met enkele aanbevelingen met betrekking tot praktische implicaties en worden suggesties gedaan voor toekomstig onderzoek.

Northern Centre for Healthcare Research (NCH) and previous dissertations

Northern Centre for Healthcare Research (NCH) and previous dissertations

The Northern Centre for Healthcare Research (NCH) was founded in 1986 as a research institute of the University of Groningen (RUG), The Netherlands. Researchers from both the Medical and the Social Faculty, with various professional backgrounds, are members of the NCH. These include medical sociologists, medical doctors, psychologists and human movement scientists. Research of the NCH is aimed at optimising quality of life of patients and quality of healthcare, and focuses on (a) determinants of health and illness, (b) consequences of illness, (c) the effects of medical treatment and decision making, and (d) the evaluation of health services and various types of interventions. At the time that this thesis is published, the NCH comprises five research programs.

Until 1998, the NCH covered two research programs, i.e. 'Determinants of Health' and 'Medical Decision Making and Evaluation of Healthcare'. The first program was reformulated in 1996 and was continued as 'Disorder, Disability and Quality of Life' (DDQ). Hence, previous dissertations in this area are listed as part of the present DDQ-programme. The second program was subdivided in 1998 into two new programs, i.e. 'Public Health and Public Health Services Research' and 'Rational Drug Use'. Dissertations published earlier within the second program are listed retrospectively under these new headings. In 1998, two new programs, 'Rehabilitation Programs Research' and 'Research in Motor Behaviour', were formulated and officially integrated in the NCH in January 1999. The accomplished dissertations since the start of the programs in 1998 are included in the list. In 2000 the Department of General Practice joined the NCH and together with the Rational Drug Use group initiated a new research program, i.e. 'Research in Evidence Based Medicine'.

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REFERENTEN: dr R Sanderman, dr ThPBM Suurmeijer

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REFERENTEN: dr FLP van Sonderen, dr R Sanderman

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PROMOTORES: prof dr WJA van den Heuvel, prof dr W Molenaar.
REFERENT: dr ThPBM Suurmeijer

Sanderman R (1988) *Life events, mediating variables and psychological distress: a longitudinal study.* PROMOTORES: prof dr WJA van den Heuvel, prof dr PE Boeke, prof dr PMG Emmelkamp. REFERENT: dr J Ormel

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Dekker GF (1995) *Rugklachten-management-programma bij de Nederlandse Aardolie Maatschappij B.V.: ontwerp, uitvoering en evaluatie.* PROMOTORES: prof dr D Post, prof WH Eisma. CO-PROMOTOR: dr JW Groothoff

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Engelsman C & Geertsma A (1994) *De kwaliteit van verwijzingen.* PROMOTORES: prof dr WJA van den Heuvel, prof dr FM Haaijer-Ruskamp, prof dr B Meyboom-de Jong

Lucht F van der (1992) *Sociale ongelijkheid en gezondheid bij kinderen.* PROMOTOR : prof dr WJA van den Heuvel. REFERENT: dr JW Groothoff

Research in Evidence Based Medicine

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supplementation with alpha-linolenic acid.
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CO-PROMOTOR: dr JF May. REFERENTEN: dr J Broer, dr EJM Feskens, dr FW Siero, dr AJ Smit

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Rehabilitation Programs Research (from 1998 onwards)

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REFERENT: dr MHG de Greef

Berkhuysen MA (1999) *Toward tailor-made cardiac rehabilitation: getting at the heart of the matters.* PROMOTORES: prof dr AP Buunk,
prof dr P Rispens. REFERENT: dr R Sanderman

Dankwoord

Dankwoord

In vrijwel elk dankwoord van ieder proefschrift wordt vermeld dat een proefschrift niet tot stand komt door de inspanningen van de promovendus alleen. In het geval van de MIEP-studie is dat ook zeker het geval; net als diabeteszorg zelf en diabetesrevalidatie in het bijzonder is het schrijven van een proefschrift over dit onderwerp teamwork. Nadenkend over wie allemaal heeft bijgedragen aan de totstandkoming van dit proefschrift ga ik me haast afvragen waar ik het zelf toch zo druk mee gehad heb.

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Thera, ik heb je enthousiasme, energie en betrokkenheid altijd geweldig stimulerend gevonden bij het werk van de afgelopen vierenhalf jaar. Naast je vele andere drukke werkzaamheden maakte je altijd tijd om mijn stukken te lezen, mee te denken over de uitvoering van het onderzoek en ben je onmisbaar geweest bij het vertalen van de bevindingen van het onderzoek naar het verder ontwikkelen van diabetesrevalidatie en bij het kweken van draagvlak voor deze benadering.

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Het team van de afdeling diabetesrevalidatie bood eveneens een gezellige en stimulerende werkomgeving. Ik ben me helemaal lid gaan voelen van het team en niet een onderzoeker die toevallig onderzoek deed bij patiënten van deze afdeling. Het secretariaat heeft me geweldig geholpen bij het benaderen van revalidanten voor het onderzoek, het complementeren van alle gegevens en het versturen van de MIEP nieuwsbrief. Janine Kramer en Elsa Pieterman waren voor het grootste deel van de tijd de vaste secretaresses. Hartelijk dank voor jullie grote hulp en dat ik jullie altijd kon vragen of een bepaalde patiënt nu wel of niet meedeed aan MIEP en wat zijn HbA1c was. Henny Meijer wil ik bedanken voor de nauwgezette en betrokken wijze waarop zij de telefonische interviews deed. Henny, je inzet om alle revalidanten telefonisch te kunnen bereiken en de precieze verslaglegging van de interviews waren van grote waarde voor dit onderzoek. De teamleiding, eerst Riemie Kalsbeek en nu Rita Wesselius, heeft het mogelijk gemaakt dat het onderzoek integraal deel uitmaakte van het werk van de afdeling en dat de samenwerking wordt voortgezet. Ik heb het zeer op prijs gesteld om te worden betrokken bij allerlei activiteiten van de afdeling, zoals het verzorgen van de stand op de diabetesdagen.

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